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**Table 4.** Proposal for definition of disease-free survival for neoadjuvant treatment trials incorporating the option of non-operative management

<b>Event</b>	<b>DFS</b>	<b>Time from randomisation until*</b>
No resection of primary tumour due to local progression or patient unfit for surgery	E	date of exploratory surgery or date of scheduled, but not performed surgery
No resection of primary tumour due to clinical complete response; patient opts for NOM	I	-
Limited surgery (LE/TEM) of primary tumour due to (near) clinical complete response (including curative completion TME after initial LE/TEM)	I	
Non-radical resection of primary tumour (R2-resection)	E	date of surgery
Locoregional recurrence after R0/1 resection of the primary tumour	E	date of locoregional recurrence
Local re-growth after initial clinical complete response followed by curative salvage operation (R0/1) <sup>§</sup>	I	-
Non-salvageable local regrowth in case of NOM management (no operation or R2 salvage resection)	E	date of diagnosis of non-salvageable re-growth or date of R2 salvage surgery
Any distant metastatic disease before, at, or after surgery or NOM management	E	date of distant metastases
Second primary colorectal cancer	E	date of second colorectal primary
Second primary, other cancer	E	date of second primary, other cancer
Treatment-related death	E	date of death
Death from same cancer	E	date of death
Death from other cancer	E	date of death
Non-cancer related death	E	date of death
Lost to follow-up	C	date last follow-up

E = event; I = ignore; C = censor; \*whichever occurs first; NOM, nonoperative management; LE = local excision, TEM = transanal endoscopic microsurgery, TME = total mesorectal excision

<sup>§</sup>If a local excision is performed for local regrowth after initial clinical complete response and, subsequently, a local recurrence occurs, then a salvage operation should be performed. If the salvage operation for the local recurrence is performed in curative intent (R0/1), it should not count as an event (“ignore”). If, however, no operation, or only a R2 resection is possible, or there is a recurrence after salvage surgery, this should count as an event.