

BACKGROUND

Bladder cancer is the 10th most common cancer in the UK. Around 10,000 new cases are diagnosed yearly. Strongly associated with smoking, it is 3-4 times more prevalent in men. Mean age at diagnosis is 70yrs and co-morbidities are common amongst these patients.

USUAL TREATMENT

- Surgical removal of the bladder has been standard care for a long time after which:
 - most patients have urinary diversion with a tube to a bag on the abdomen (stoma)
 - a small number of patients have a new bladder (neo-bladder) constructed
- ❖ Radiotherapy is used for those unfit for surgery or who wish to keep their bladder
- ❖ Chemotherapy now instituted for a 1/3rd of patients prior to surgery or radiotherapy

UNCERTAINTY

- ❖ By 2007 a top question for UK Urology = **"WHICH TREATMENT IS BEST?"**
- ❖ 2010 - SPARE RCT (surgery Vs radiotherapy) closed due to failure to recruit¹
- ❖ Meanwhile survival data appears increasingly similar for the two treatments and NICE recommends patients are given the choice between them²
- ❖ But there remains a lack of comparative data to enable informed choice³

AIMS

Investigate quality of life after treatment to:

- aid decision-making for patients & their families
- enable the clinical community to better support patient choice

ELIGIBILITY

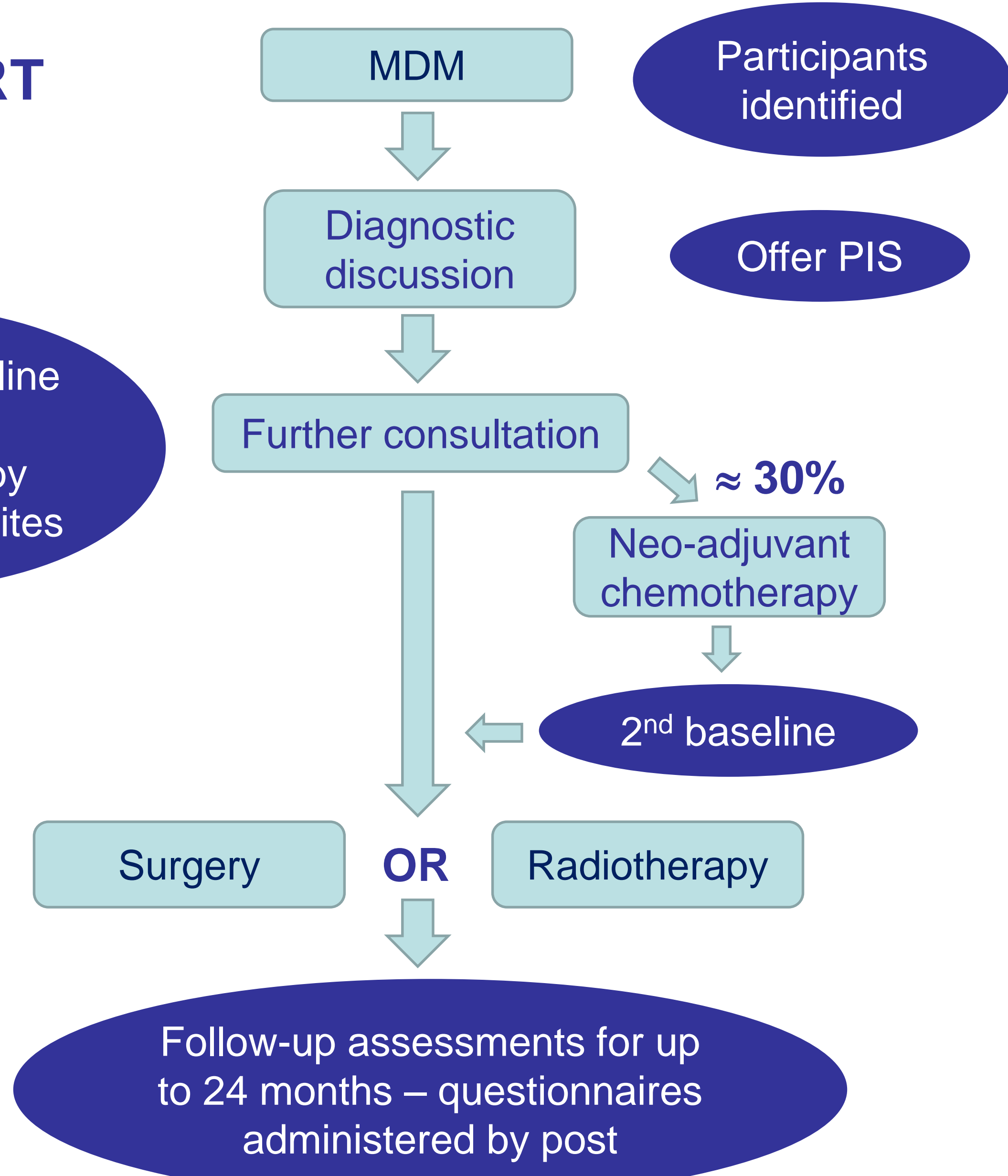
Patients with muscle invasive bladder cancer:

- newly diagnosed or following a history of non-invasive disease
- commencing treatment with curative intent
- equally eligible for surgery or radiotherapy
- English language sufficient to complete questionnaires

METHODS

- ❖ Prospective, longitudinal, observational study
- ❖ Contemporaneous comparative 2 cohort design (surgery Vs radiotherapy)
- ❖ Patient reported outcomes collected using validated questionnaires
- ❖ Clinical outcomes captured with CRFs completed by clinical staff at NHS sites
- ❖ Health Economic evaluation undertaken by University of Surrey

FLOW CHART



OUTCOMES

PRIMARY – quality of life (FACT-Bladder⁴)

SECONDARY - fear of cancer recurrence, overall survival & disease recurrence (local & distant), treatment related side-effects (patient & clinician reported), financial impacts

Assessment schedule	Baseline	2 nd Baseline	End of treatment	Follow-up after surgery or radiotherapy				
				3 month	6 month	9 month	12 month	24 month
FACT-BL ⁴	✓	✓			✓		✓	✓
Fear of Recurrence scale (Kornblith ⁵)	only some items						✓	✓
EQ-5D-5L	✓	✓		✓	✓	✓	✓	✓
Service use questionnaire	✓			✓	✓	✓	✓	
Clinical data CRF	✓		✓				✓	✓



FACT-BI (Version 4)

Below is a list of statements that other people with your illness have said are important. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	Not at all	A little bit	Some-what	Quite a bit	Very much
PHYSICAL WELL-BEING					
Q1 I have a lack of energy	0	1	2	3	4
Q2 I have nausea	0	1	2	3	4

FEARS ABOUT CANCER (FOR SCALE - Kornblith 1997)

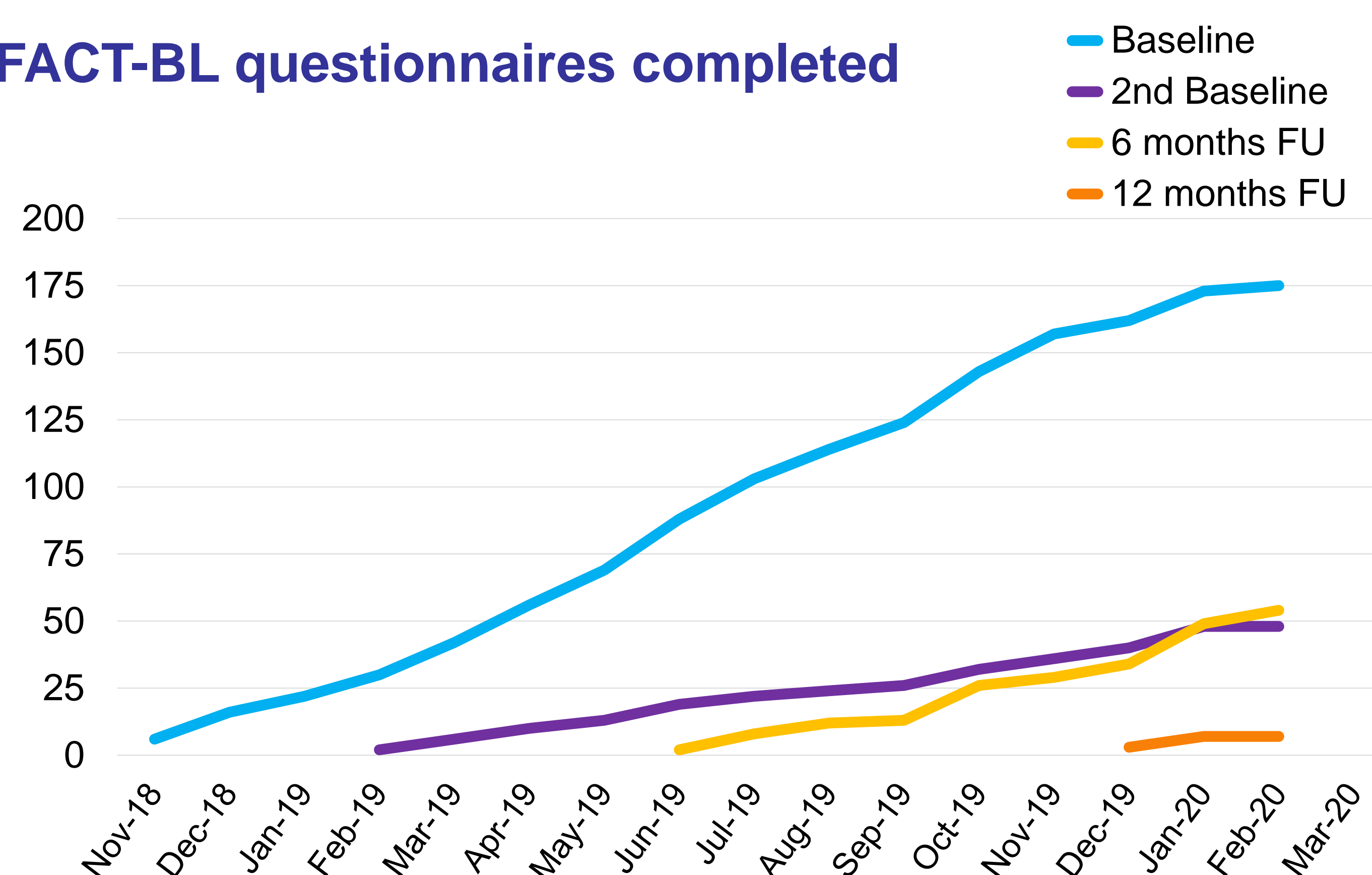
Listed below are a number of statements concerning cancer patients' beliefs about having had cancer. In thinking about the past week, please indicate how much you agree or disagree with each statement: Strongly Agree, Agree, Not Certain, Disagree, or Strongly Disagree. [Please circle the number of your answer.]

Statement	Strongly Agree	Agree	Not Certain	Disagree	Strongly Disagree
1. Because cancer is unpredictable, I feel I cannot plan for the future.	1	2	3	4	5

STATUS TO-DATE

- ❖ 35 sites open in the UK
- ❖ 175/376 recruited at 12 Feb' 2020 (target = 188 per cohort)
- ❖ Health economics targeted to recruit 150 with 135 already entered
- ❖ Those enrolled are between 34-89yrs (mean 72yrs); 78% male, 22% female
- ❖ There have been 8 deaths and 18 withdrawals

FACT-BL questionnaires completed



FINAL REMARKS

- ❖ Recruitment is projected to close Dec' 2020
- ❖ A qualitative interview study complementing the Q-ABC data has already been completed by Dr Sally Appleyard as part of her MD

References:

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- Degboe et al. *Support Care Cancer* 2019; 27(11): 4189-4198.
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