Introduction & Objectives: The diagnostic pathways and outcomes for bladder cancer have remained largely unchanged for 30 years. We established the BladderPath trial with the objectives of improving staging, accelerating treatment, and reducing iatrogenic tumour spread in patients with MIBC by avoiding TURBT. The hypothesis being tested is that substituting TURBT with mpMRI will avoid unnecessary surgery, reduce the time to correct treatment for MIBC, and ultimately improve clinical outcomes.

Materials & Methods: A randomised phase 2/3 trial of standard of care (Pathway 1) versus risk-stratified mpMRI-directed care (Pathway 2) in the setting of visually-diagnosed incident bladder cancer. Eligible patients have bladder lesions suspicious for malignancy identified at flexible cystoscopy and are subsequently stratified by a 5-point Likert scale: strongly agree (1) or agree (2) that the lesion is NMIBC, equivocal (3) that the lesion is NMIBC or MIBC, and agree (4) or strongly agree (5) that the lesion is MIBC. All patients are randomised; those with probable NMIBC (Likert 1 & 2) undergo TURBT in both pathways, and those with possible MIBC (Likert 3-5) undergo TURBT (Pathway 1) or mpMRI (Pathway 2). See Figure. Primary endpoints are feasibility, time to correct therapy for MIBC, and clinical progression-free survival. Here we report preliminary feasibility data.
Results: To date, 218 patients have been registered as potentially eligible; 151 patients did not have bladder lesions on cystoscopy & 5 were excluded for other reasons. Of 62 patients randomised, we report preliminary data on 45. Of 21 patients in Pathway 1, 11 patients classified as probable NMIBC underwent TURBT (pathology: 11/11 NMIBC); 9 of 10 patients classified as possible MIBC underwent TURBT (pathology: 4/9 NMIBC & 5/9 MIBC) and one patient incorrectly underwent mpMRI (stage: MIBC). Of 24 patients in Pathway 2, 11 of 12 patients classified as probable NMIBC underwent TURBT (pathology: 9/11 NMIBC & 2/11 MIBC) and one patient incorrectly underwent mpMRI (stage: NMIBC); 12 patients classified as possible MIBC underwent mpMRI (stage: 6/12 NMIBC & 6/12 MIBC).

Conclusions: A 5-point Likert scale accurately identifies patients with probable NMIBC. It is feasible to direct possible MIBC patients to mpMRI for staging. The study is ongoing to investigate the intermediate outcome of time to correct therapy for MIBC and NMIBC, and the final outcome of clinical progression-free survival.