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Abstract 5806; First results from BladderPath: A randomised trial of MRI versus cystoscopic staging for newly diagnosed bladder cancer

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Conflicts of interest

- The authors report no conflicts of interest for this presentation

Standard diagnostic pathway

- Flexible cystoscopy → rigid cystoscopy and resection
  - Serves as tissue diagnosis and staging
  - Re-resection often needed
  - Disrupts accuracy of subsequent imaging
  - Is **not** definitive treatment for muscle-invasive disease which is often very delayed
- Most tumour sites separate tissue diagnosis and staging and use primary imaging not piecemeal resection for staging

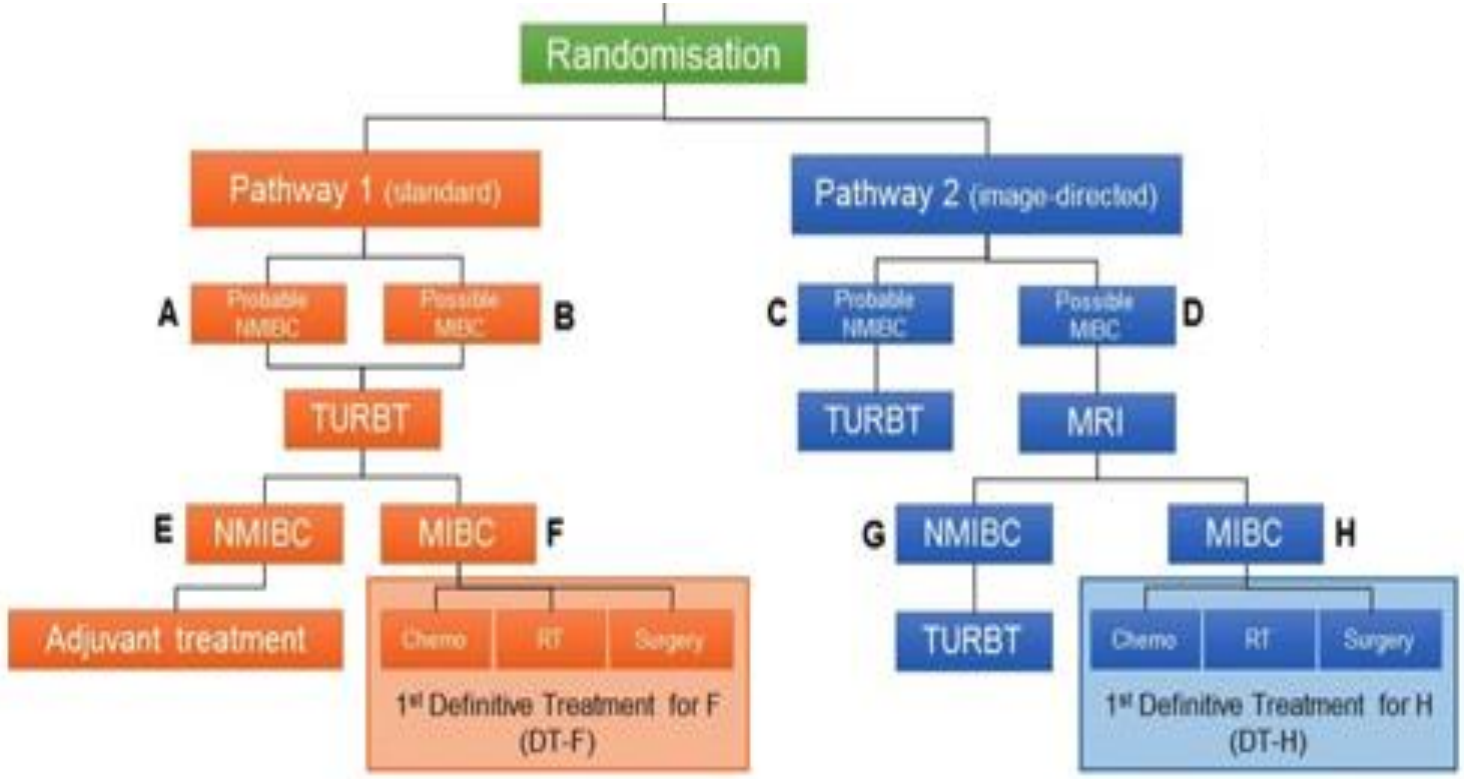
BladderPath key trial design features:

Feasibility stage

- A minimum of **80%** of patients on MRI pathway complete as planned
- Outcome Feasibility: **37/39 95%** CI (83%, 99%) followed protocol

Efficacy stage

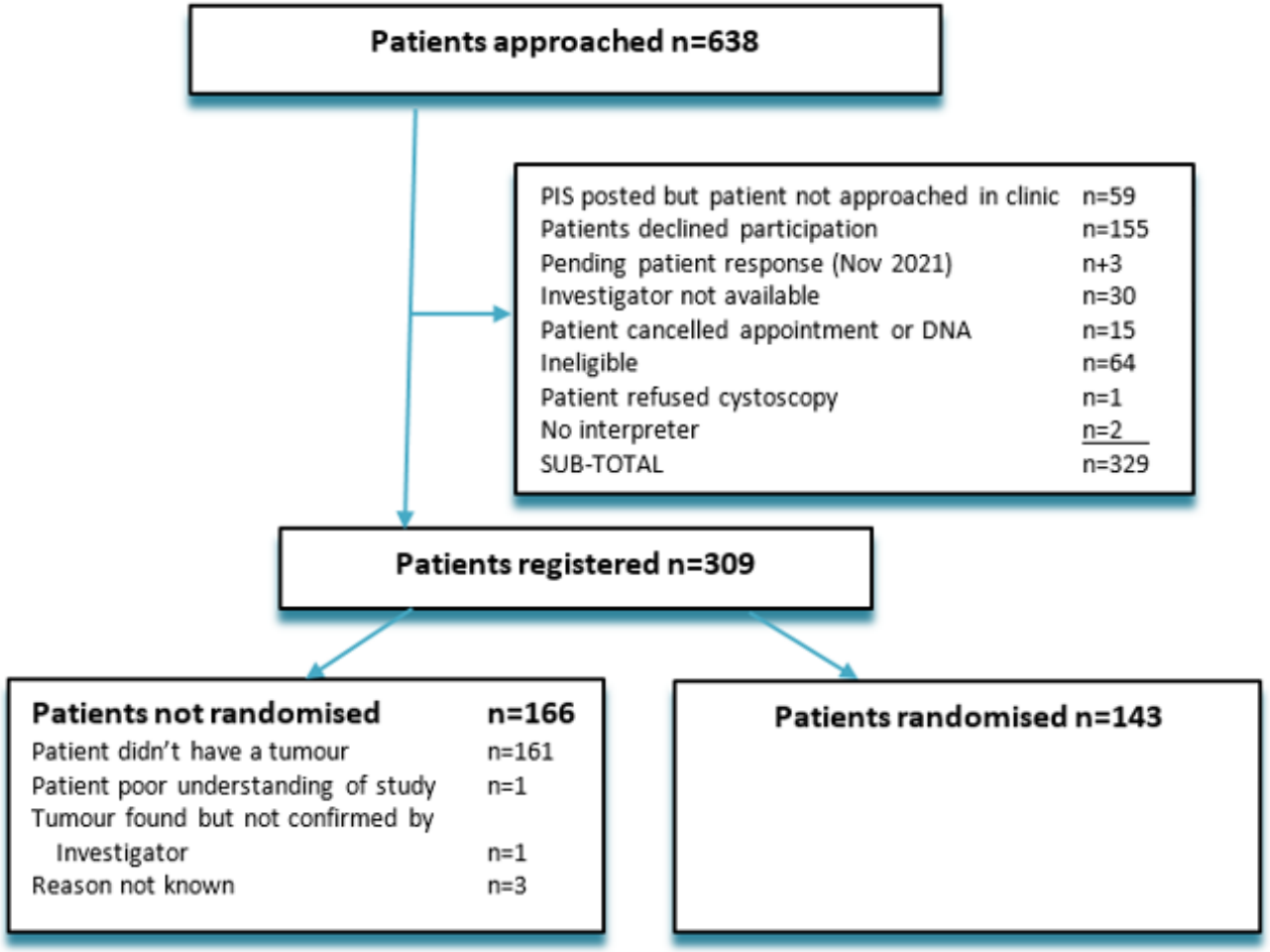
- **Primary outcome**
- A reduction of at least **30 days** in time to correct treatment (TTCT) for **muscle-invasive** bladder cancer (MIBC)
- **Secondary outcomes**
- TTCT for all patients
- TTCT for Non-MIBC



Probable non-invasive vs Possible muscle-invasive disease by clinical assessment on 5-point scale:

1. Strongly agree that the lesion is non-muscle-invasive
2. Agree that the lesion is non-muscle-invasive
3. Equivocal
4. Agree that the lesion is muscle-invasive
5. Strongly agree that the lesion is muscle-invasive

Recruitment – CONSORT Diagram



Nick James

Patient characteristics

Table 4.4: Stratification Factors by Pathway

Trt	**Pathway1 (72)**	**Pathway2 (71)**	**Overall (143)**
Sex			
Male	55 (76.4)	53 (74.6)	108 (75.5)
Female	17 (23.6)	18 (25.4)	35 (24.5)
Age			
Less Than 75	48 (66.7)	49 (69.0)	97 (67.8)
75 or Above	24 (33.3)	22 (31.0)	46 (32.2)
Iniital clinician assessment			
Probable NMIBC	34 (47.2)	32 (45.1)	66 (46.2)
Possible MIBC	38 (52.8)	39 (54.9)	77 (53.8)

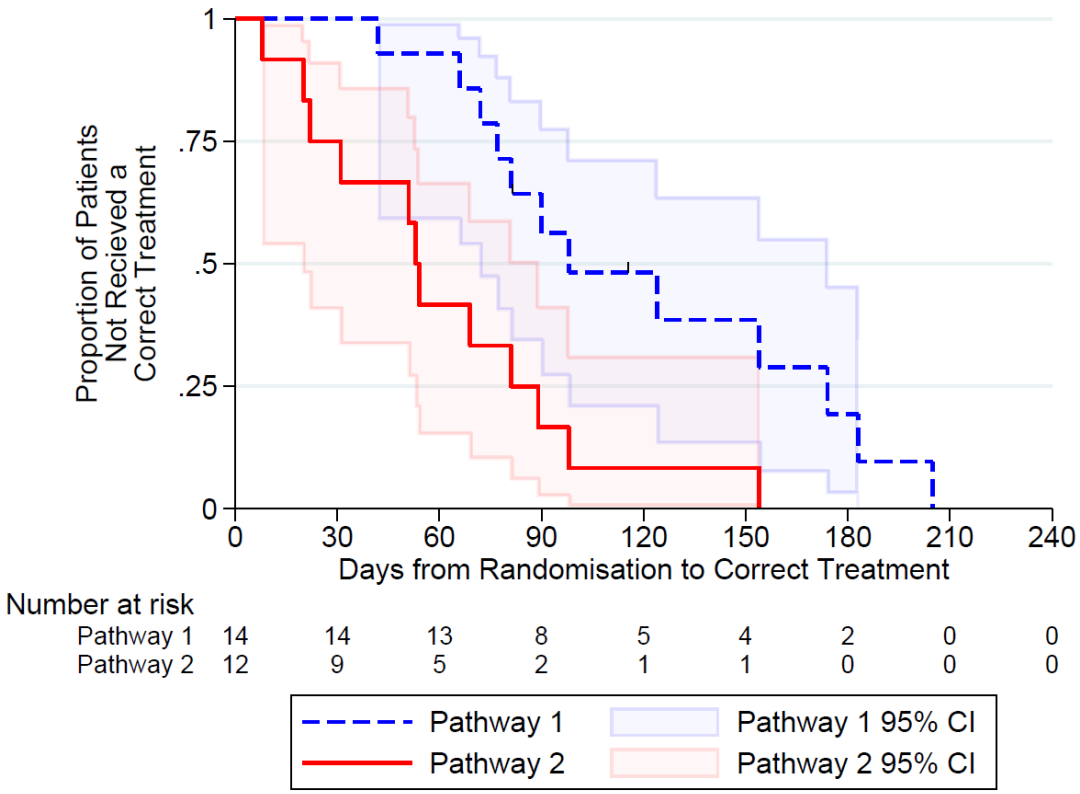
Primary Outcome for efficacy stage

Primary Outcome: Time to correct treatment (TTCT) for patients confirmed to have MIBC

- Median TTCT for pathway 1: **98 days** (95% CI. 72, 174) N=14
- Median TTCT for pathway 2: **53 days** (95% CI. 20, 89) N=12

Secondary Outcome: Time to definitive treatment (TTDT) for <u>all patients</u>

- Median TTDT for pathway 1: **23 days** (95% CI. 17, 29) N=72
- Median TTDT for pathway 2: **22 days** (95% CI. 17, 32) N=71



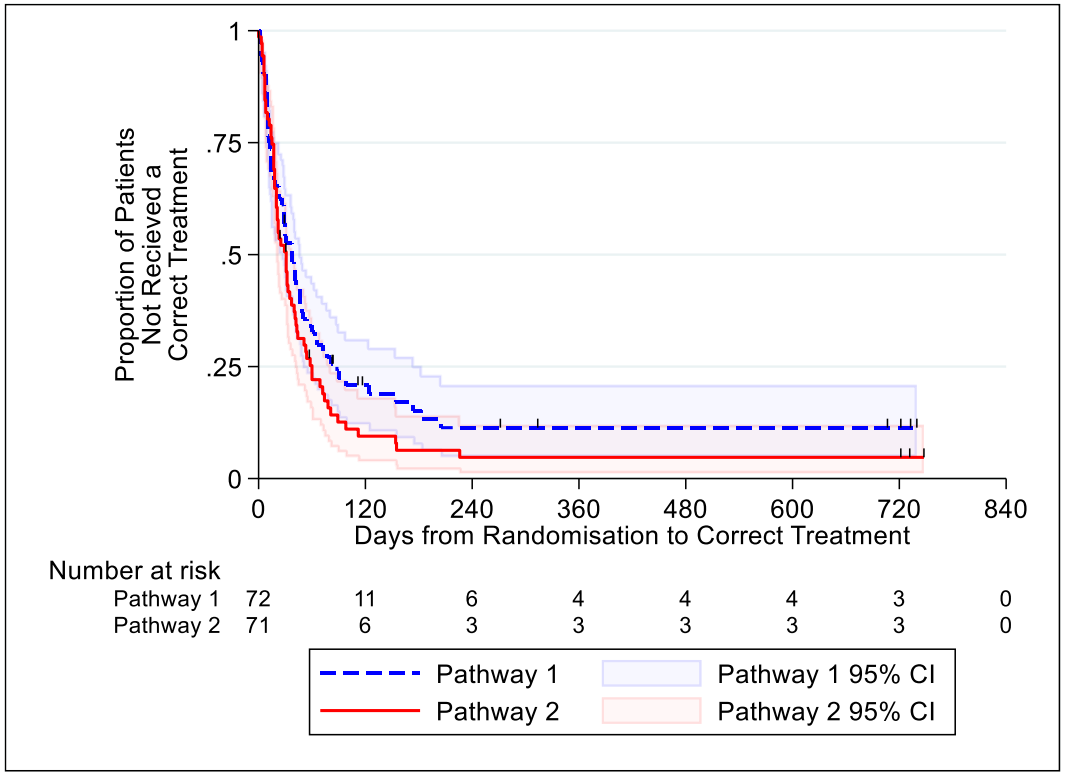
Logrank test: **p-value = 0.0046**

Cox model adjusted for gender and age : HR (Pathway 2 vs. Pathway 1) = 3.4 (95% CI. 1.4, 8.3).

Secondary Outcome: Time to correct treatment (TTCT) for all patients

- Median TTCT for pathway 1: 37 days (95\% CI. 26, 47) N=72
- Median TTCT for pathway 2: 31 days (95\% CI. 20, 37) N=71

- Logrank test: p-value= 0.1435
- Cox model adjusted for gender and age : HR (Pathway2 vs. Pathway1)=1.3 (95% CI. 0.9, 1.8). Proportional-hazards assumption checked.



Conclusions: BladderPath

- Using a Likert scale at flexible cystoscopy accurately identifies the lower risk non-invasive cases
- An image-based pathway substantially accelerated time to definitive treatment for patients with suspected muscle-invasive disease
- There was no adverse effect on times to treatment for non-invasive disease
- Patients with obvious muscle-invasive disease can potentially avoid the need for TURBT and associated risks