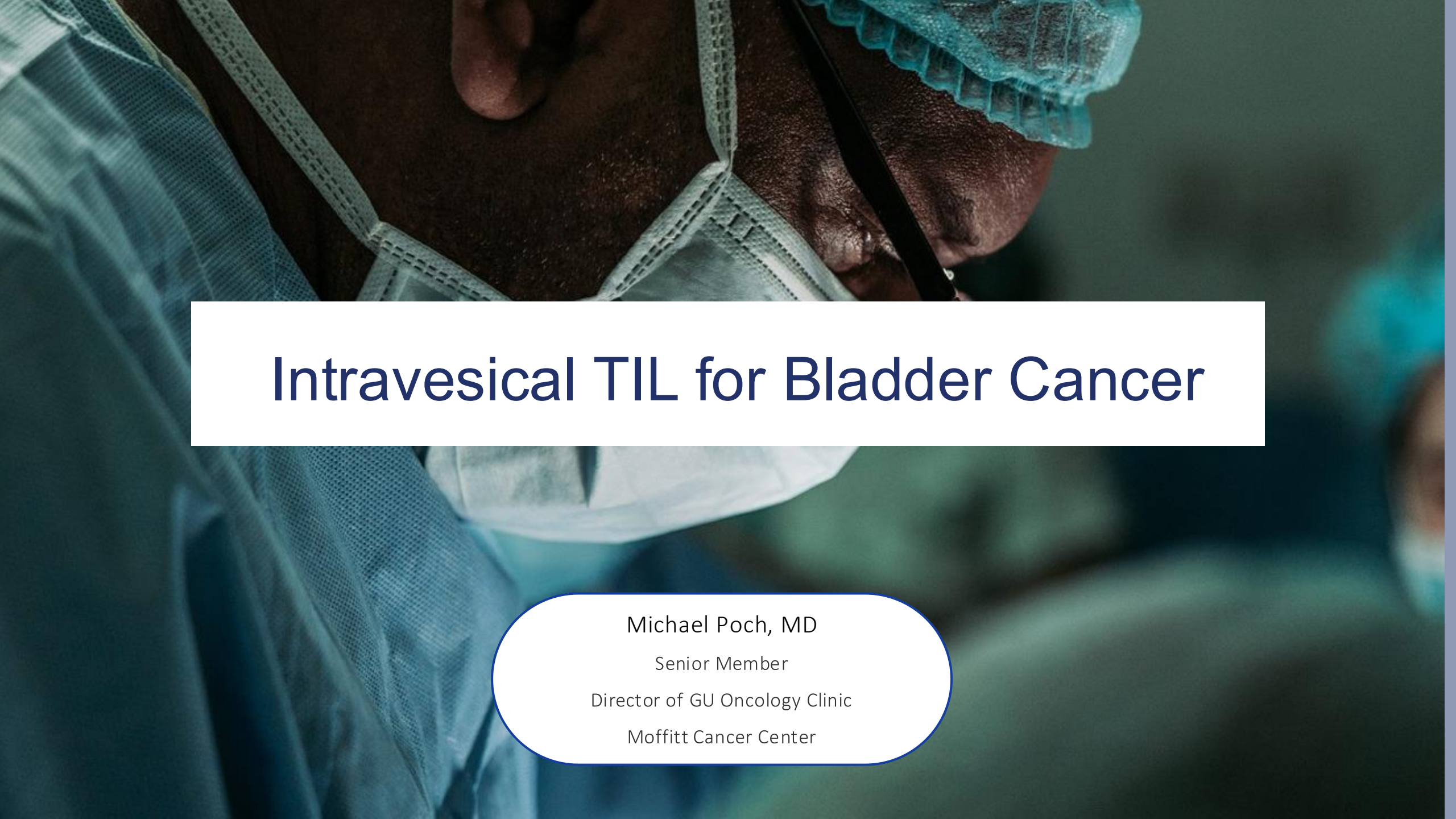




Intravesical TIL for Bladder Cancer

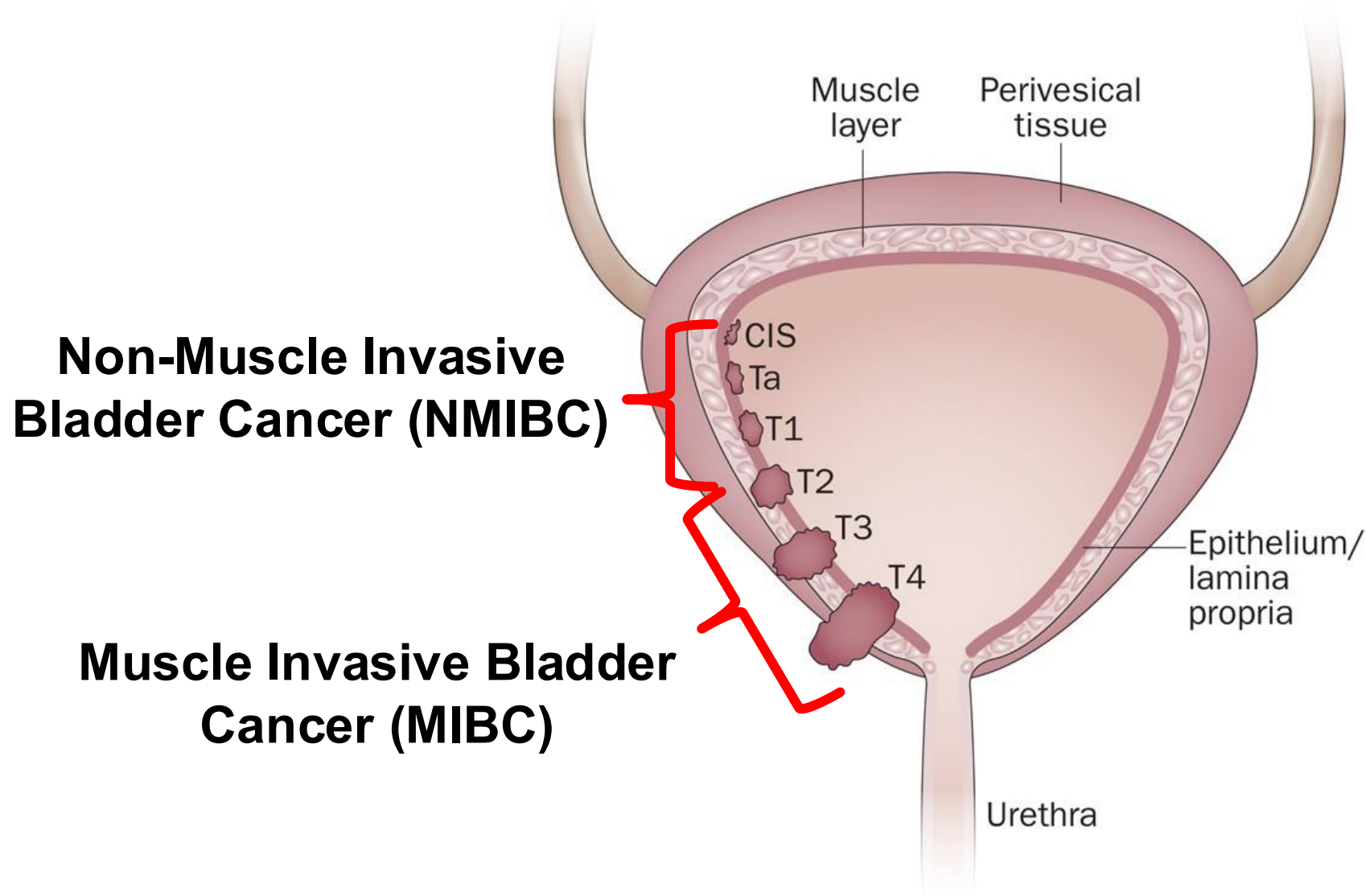
Michael Poch, MD

Senior Member

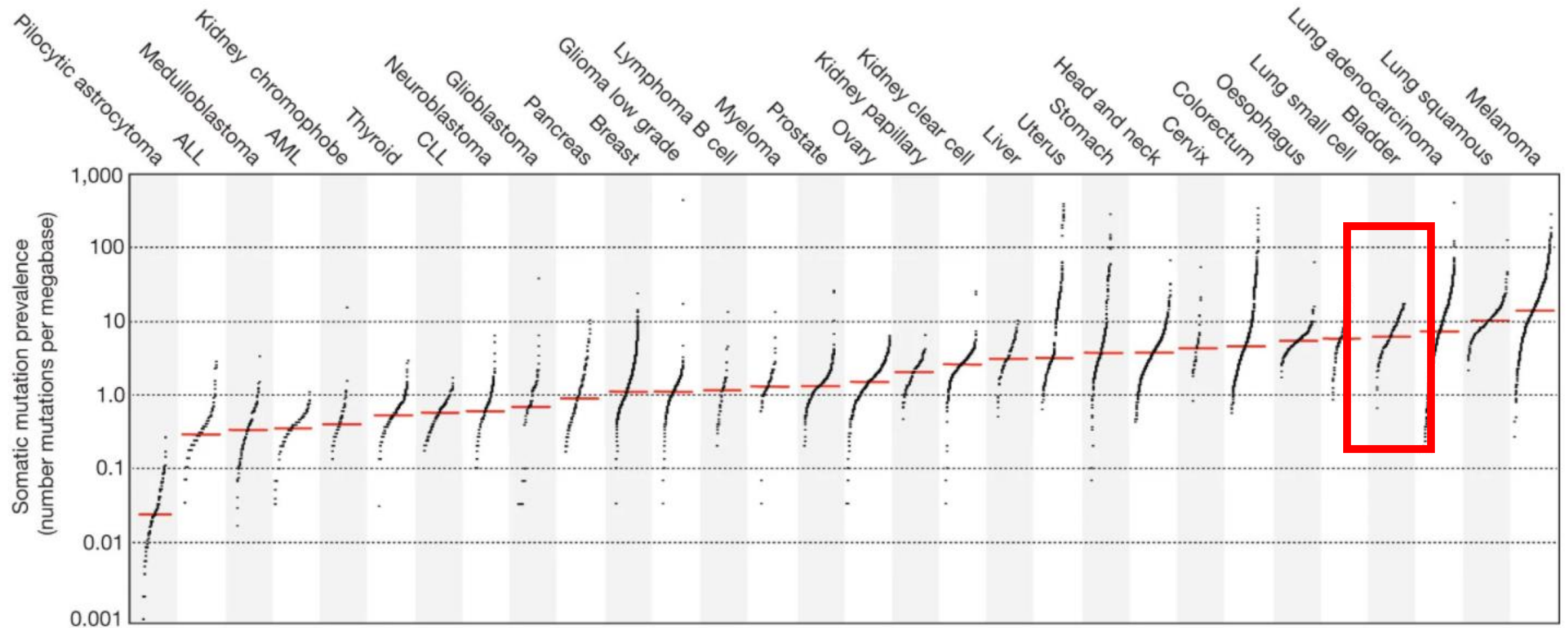
Director of GU Oncology Clinic

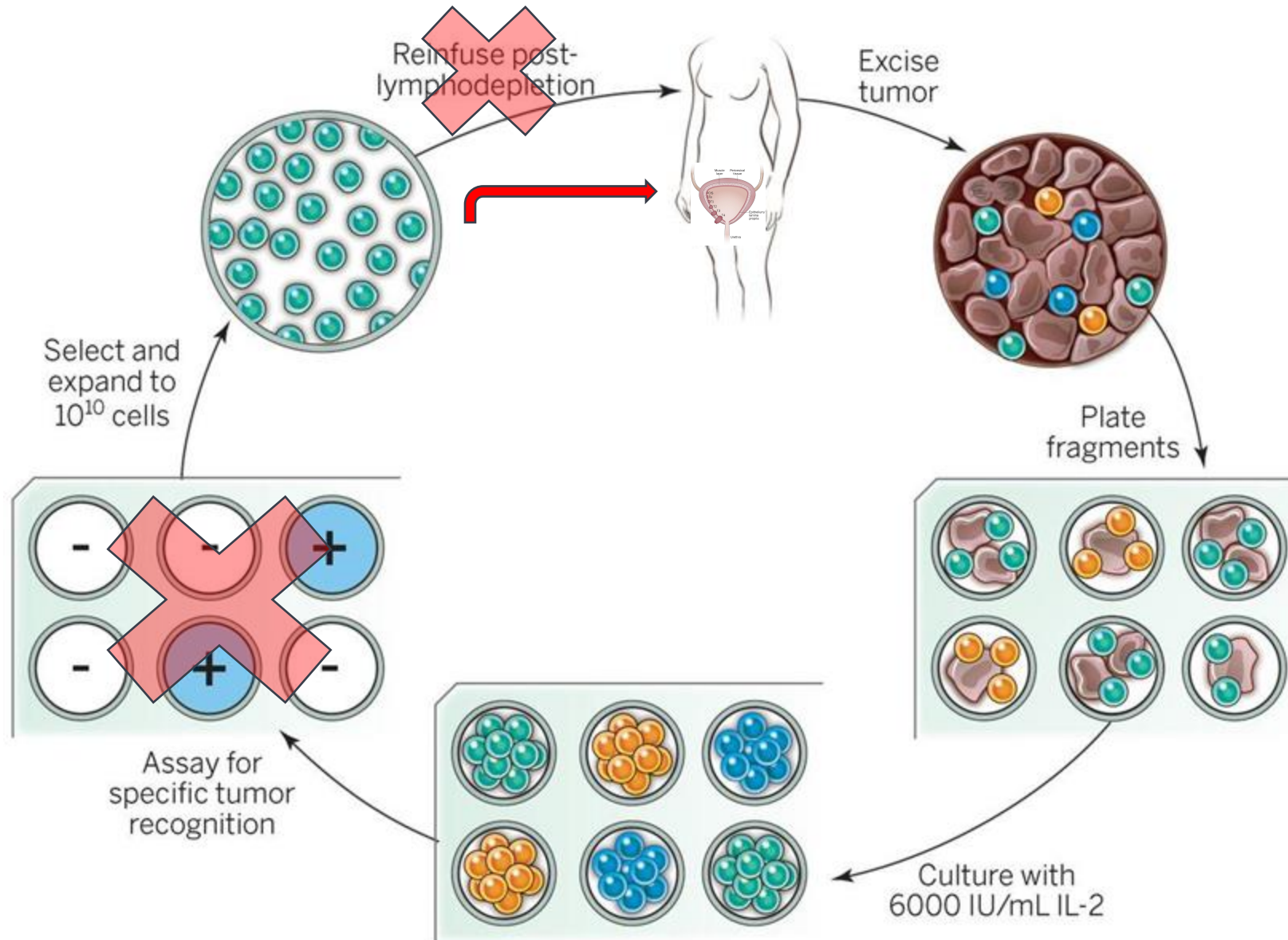
Moffitt Cancer Center

Bladder Cancer is Treated Based on Muscle Invasion



Bladder Cancer Has a High Mutation Burden





Eligibility/Screening "SS1"

- Histologically or cytologically BCG Unresponsive NMIBC (Papillary or CIS)
- ECOG 0-1
- No prior chemotherapy
- No prior PD-1/PD-L1

- N=12
- Bladder Resection

Up to 4-6 weeks
Culture

- Secondary Screening "SS2"
- PreREP

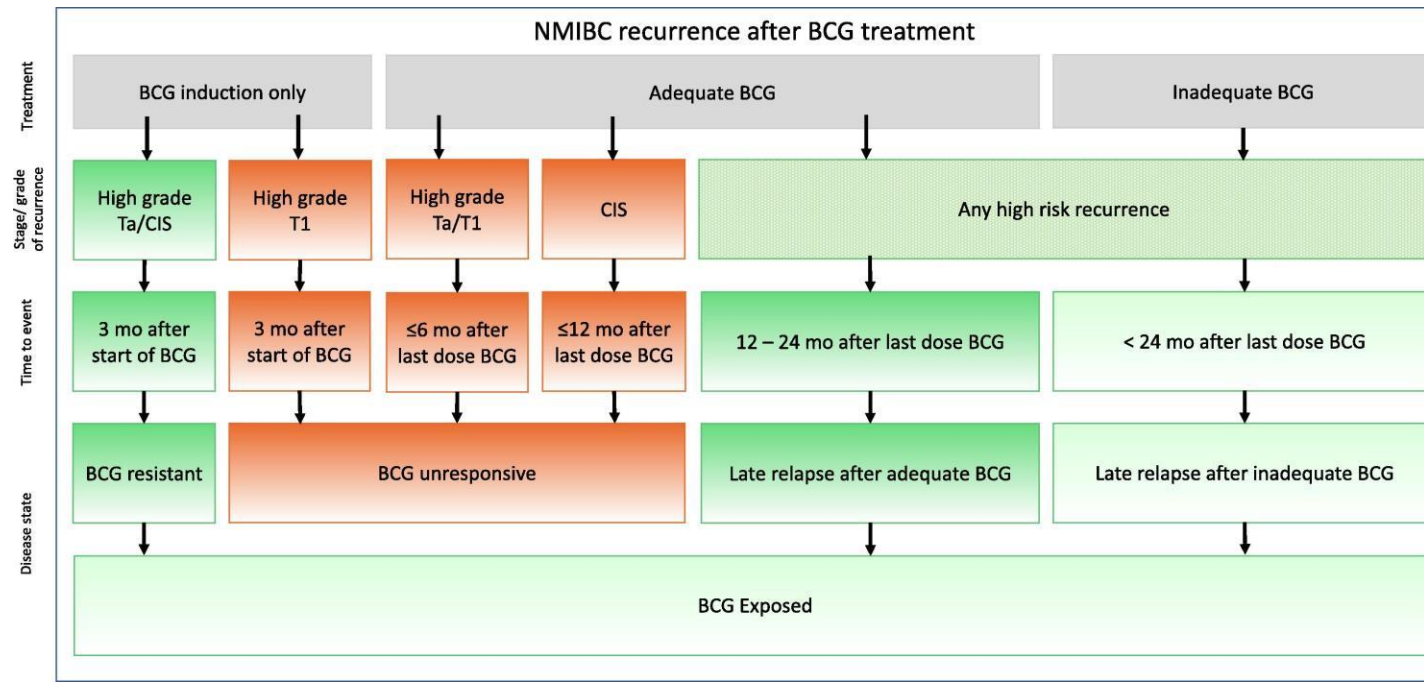
2 weeks
REP

- N~9
- **Outpatient** Intravesical ACT
- 1 x week x 4 weeks ~ 3.2×10^8 per 40 mls x 4
- Assess for AEs/DTs

6 weeks

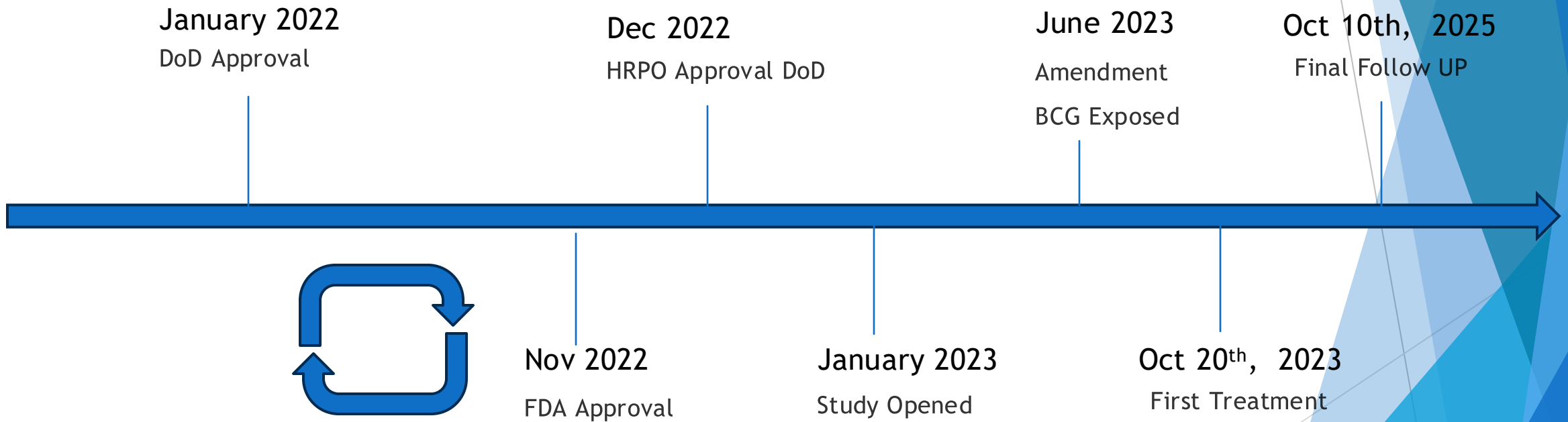
Cystoscopy

BCG Exposed





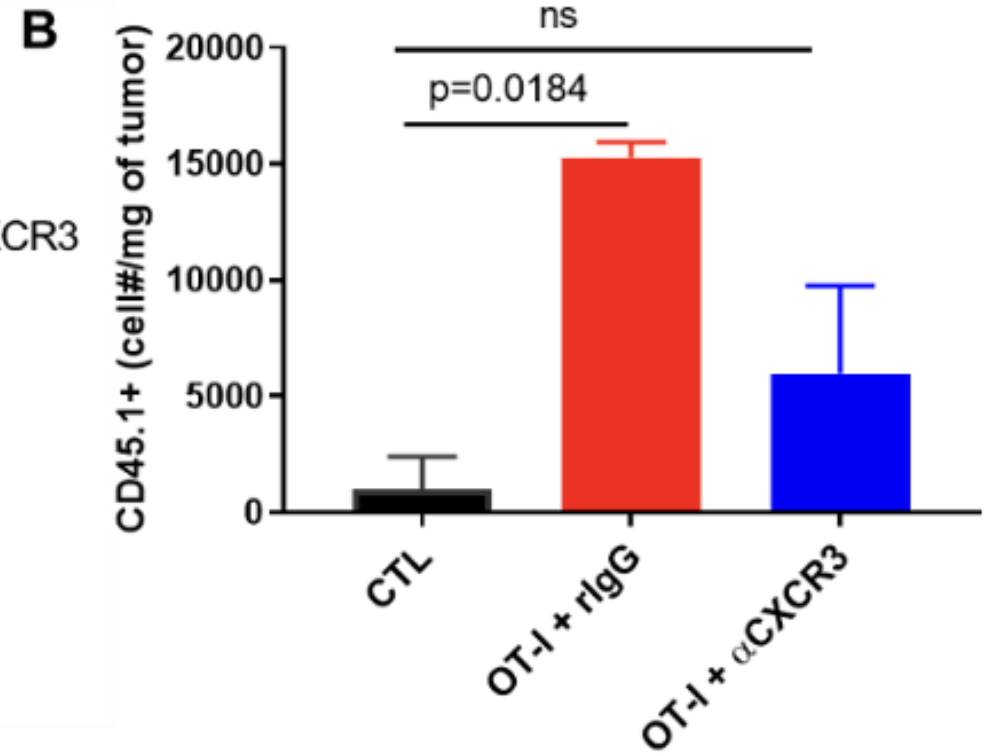
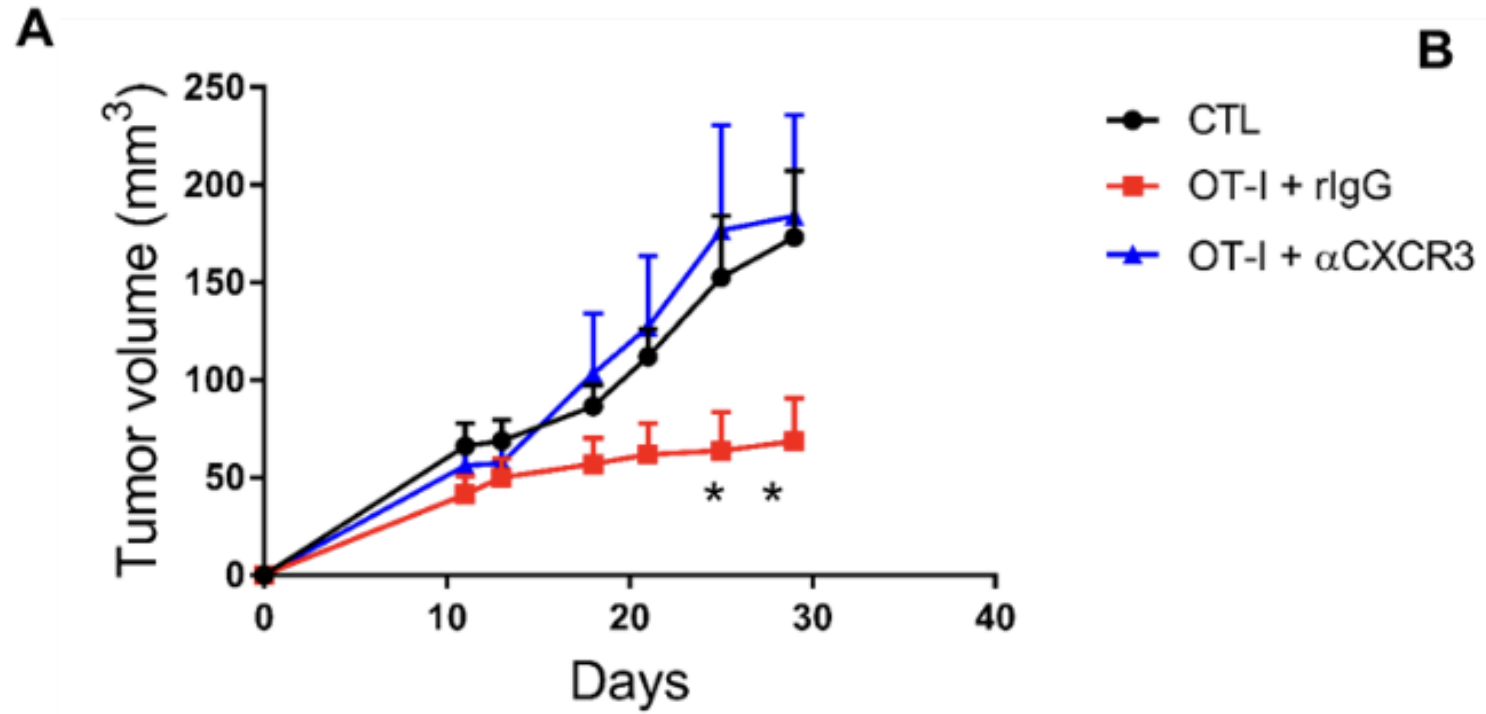
Timeline





Patient Number	Gender	Age	Number of previous bladder treatments	Months from of initial Diagnosis to Enrollment	Stage @ Enrollment Resection
BLT01	M	65	3	29	HG Ta
BLT02	M	73	1	16	HGT1
BLT03	M	60	1	9	HG Ta
BLT04	M	76	1	27	HG Ta
BLT05	M	77	1	5	HG T1
BLT06	M	77	2	10	CIS
BLT07	M	84	3	28	HGTa
BLT08	M	70	3	71	HGTa
BLT09	M	64	2	35	HGTa



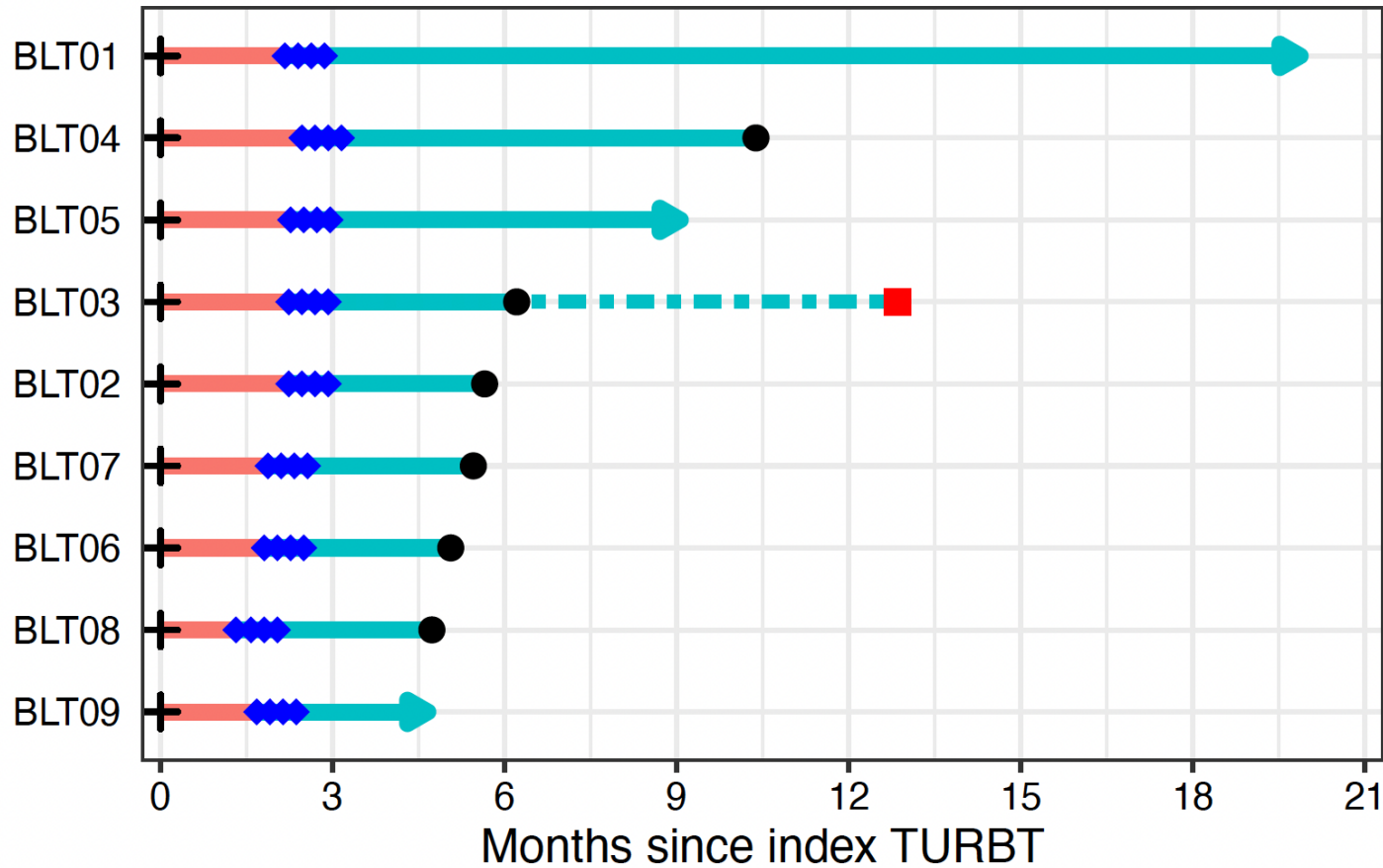




Percentage of cells in bladder				
Dose Number				
Patient Number	1	2	3	4
BLT01	87.19%	93.44%	91.78%	CE
BLT02	96.31%	76.25%	CE	93.16%
BLT03	CE	CE	CE	CE
BLT04	CE	98.79%	CE	CE
BLT05	60.31%	18.51%	33.02%	90.84%
BLT06	87.06%	94.38%	98.19%	97.02%
BLT07	93.94%	95.03%	99.14%	99.39%
BLT08	98.52%	99.33%	87.34%	94.78%
BLOT009	84.45%	80.06%	95.23%	79.82%
Average	86.82%	81.97%	84.12%	92.50%
Total Average	86.05%			

Measured from post void





Event/Status

- ✚ Resection
- ◆ TIL Infusion
- Recurrence
- Cystectomy
- TIL Harvest/Expansion
- Post-Treatment Follow-Up
- - - Post-Recurrence
- ➡ Ongoing Surveillance

TIL: Tumor Infiltrating Lymphocytes

TIL Infusion was administered once weekly for 4 weeks



Primary End Points Met

1. We can grow TIL from small tumors
2. We can treat with Intra Ves TIL
3. No grade 3 or higher Aes

Secondary End Points

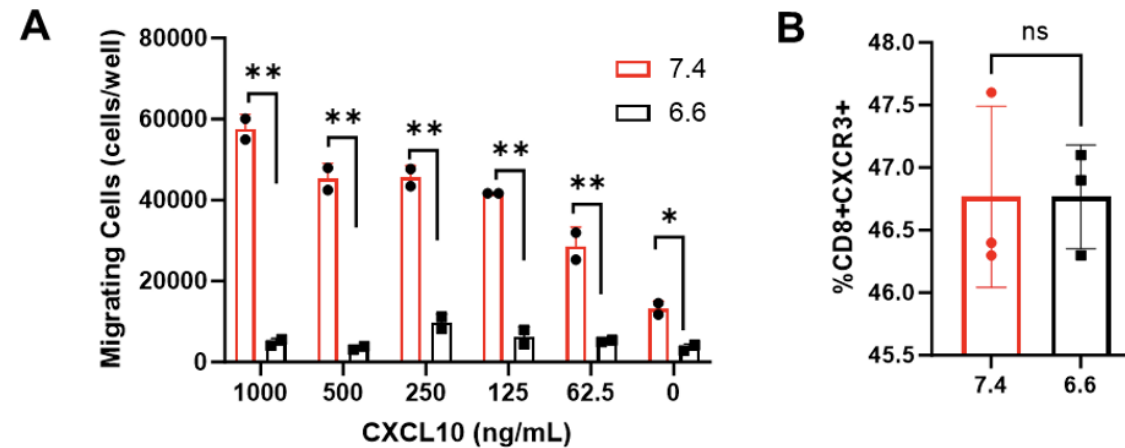
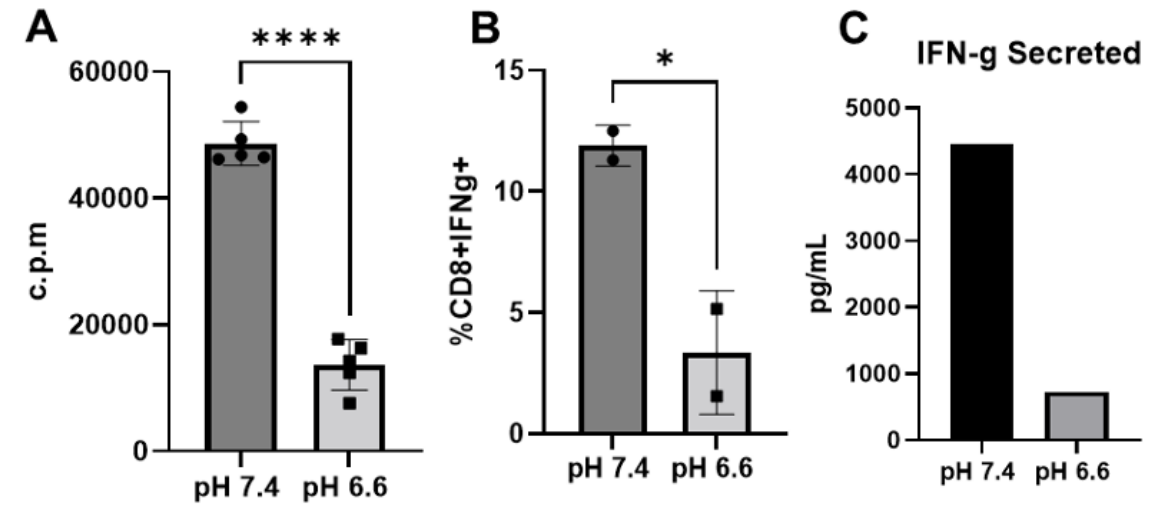
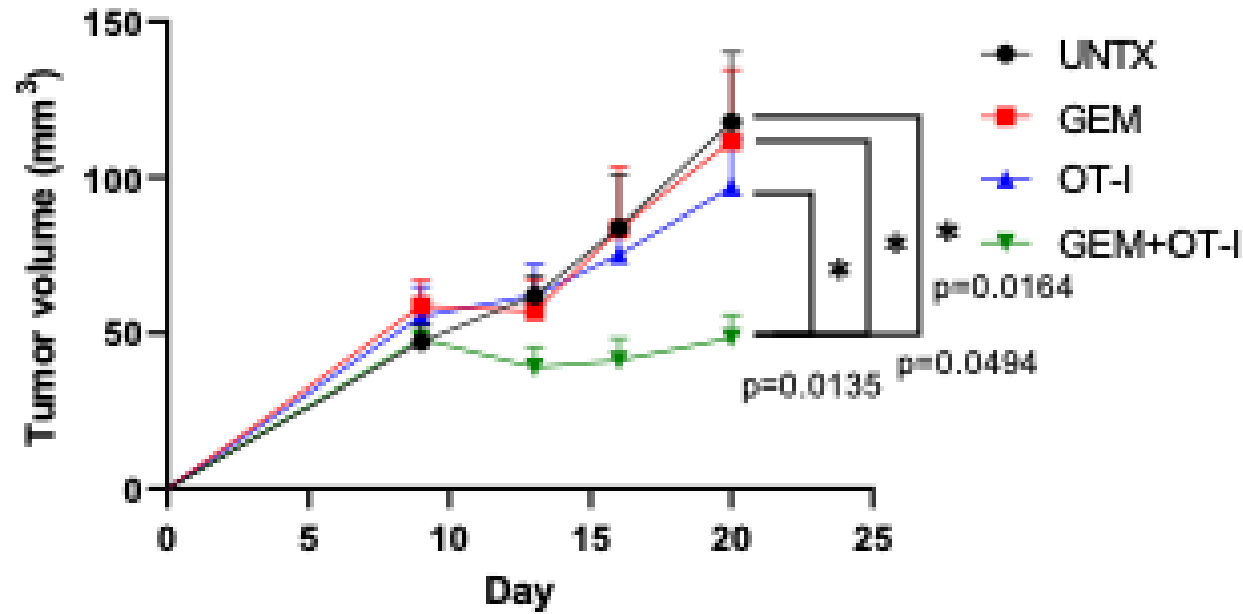
- No progression
- CR rate at 3 months was 33%

Comments

No maintenance given



The next steps



Maintenance
Therapy
5 monthly doses

Induction
Therapy
4 weekly doses

Tumor
resection

Intravesical
Tumor
Infiltrating
Lymphocytes

Tumor
Infiltrating
Lymphocyte
Expansion

Intravesical
Gemcitabine

Oral
Alkaline
Therapy

Rapid
Expansion
Protocol



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Molecular Genomics Core
Proteomics and Metabolomics Core
Biostatistics and Bioinformatics Core
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