

A Phase II Trial of Risk Enabled Therapy After Initiating Neoadjuvant Chemotherapy for Bladder Cancer (RETAIN BLADDER): Interim analysis

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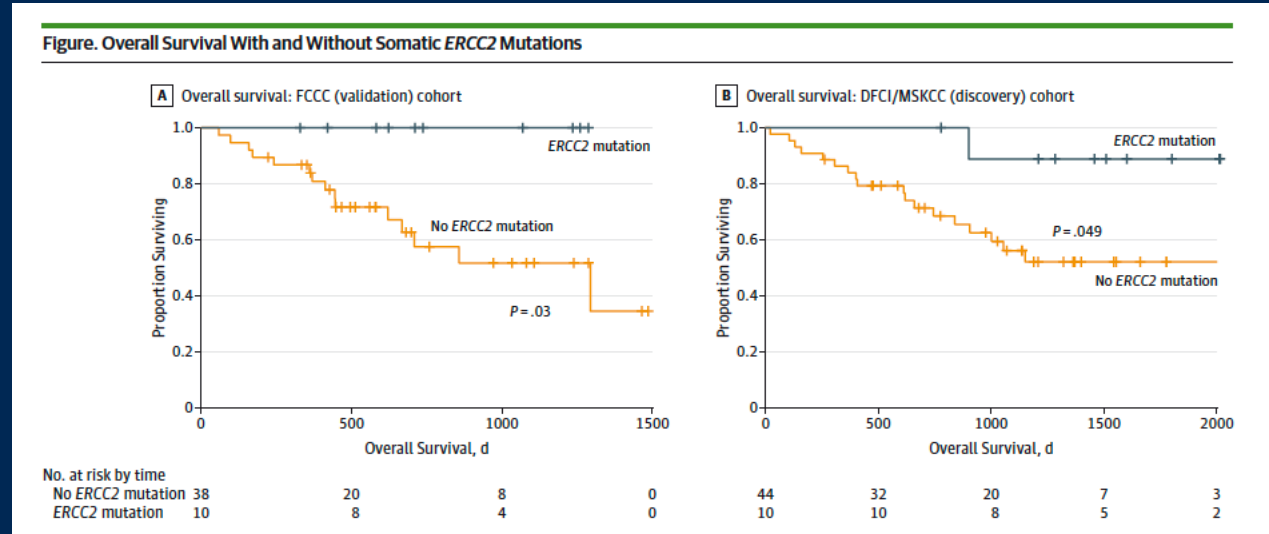
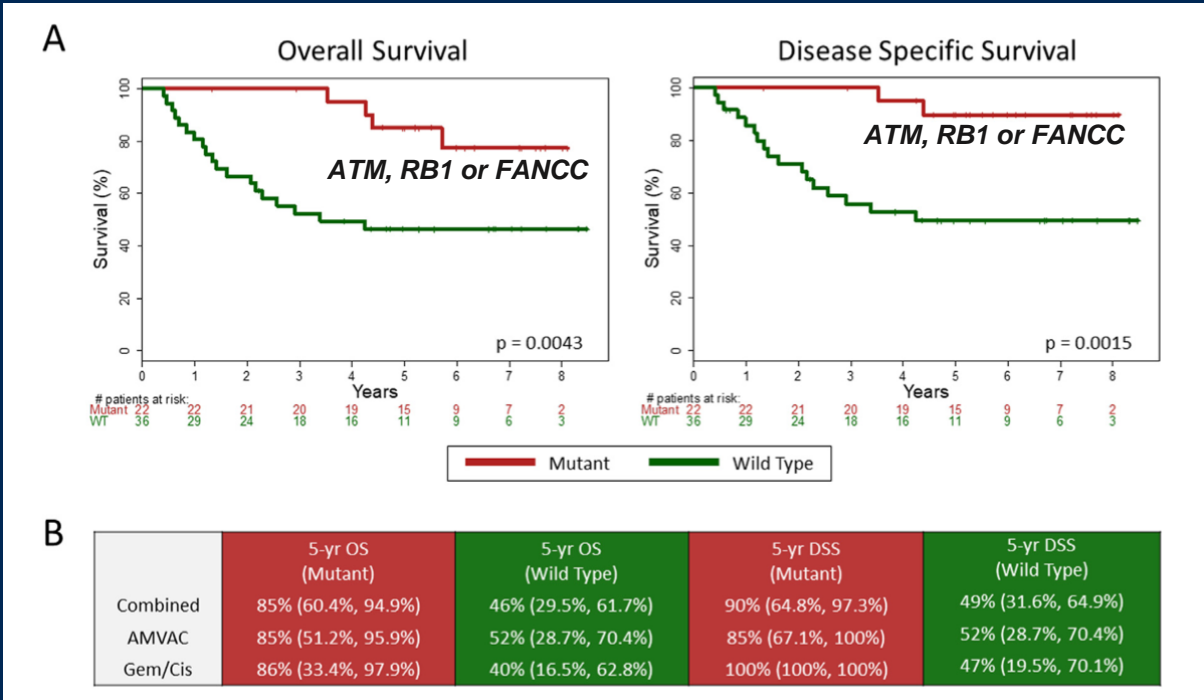
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Background

Miron...Plimack, Eur Urol Oncol, 2020

Liu...Rosenberg, JAMA Oncol 2016

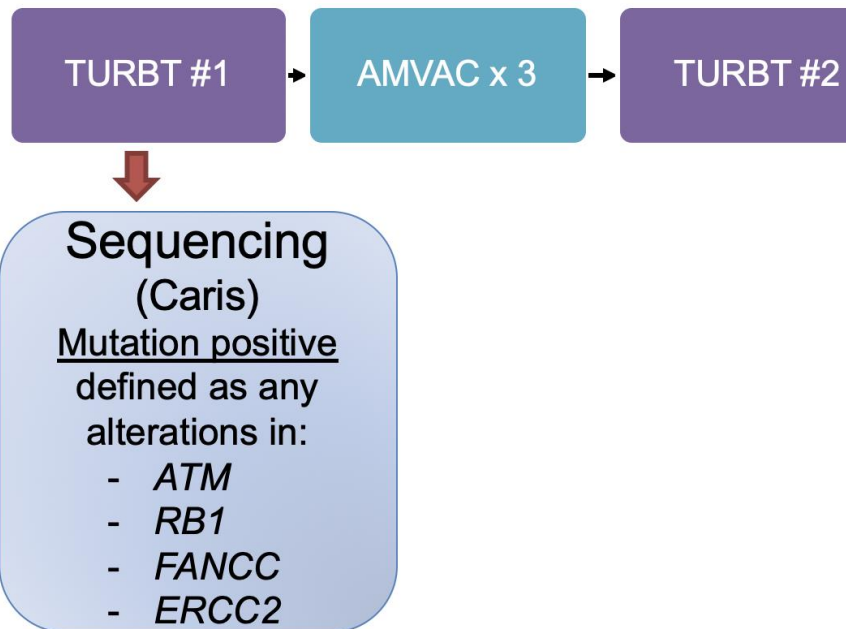


Trial Schema: NCT02710734

Major Inclusion Criteria:

- cT2-T3 N0M0
- ECOG 0-1
- Urothelial Predominant Histology

Not a randomized trial

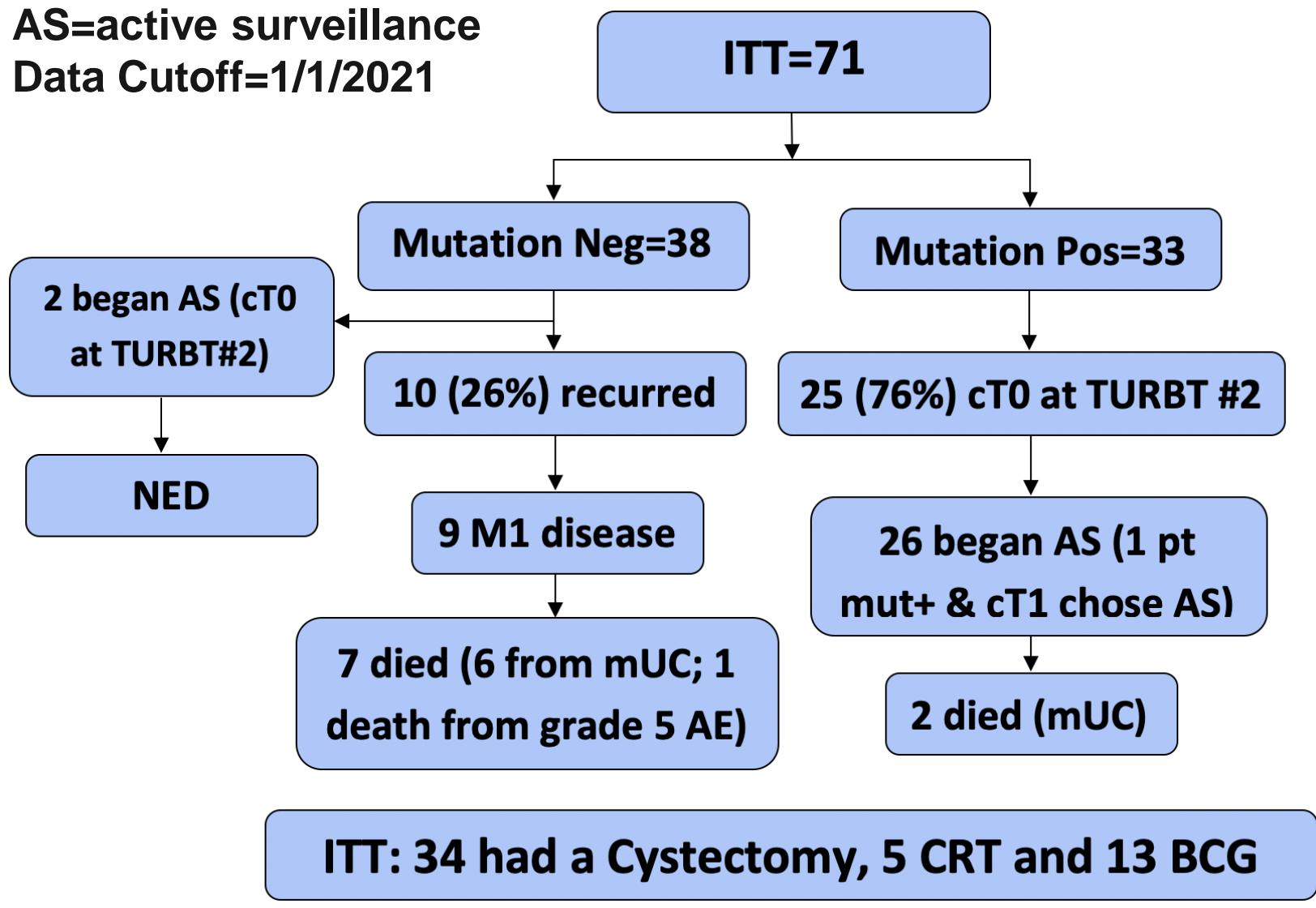


Results: Baseline Characteristics

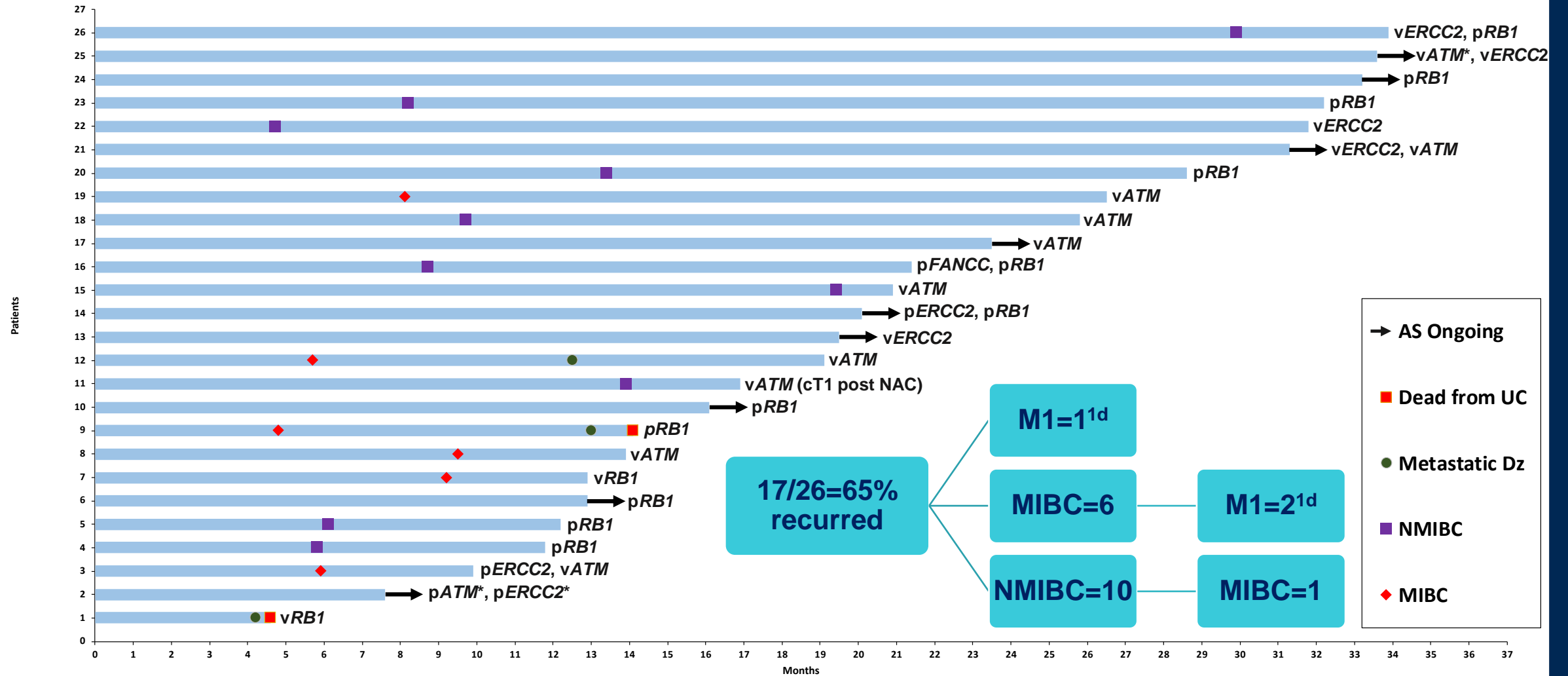
Characteristic	Number (N=71)	Percent (%)
Age		
Median	70	
Range	47-83	
Sex		
Male	54	76%
Female	17	24%
Race		
AA	3	4%
Asian	2	3%
White	66	93%
ECOG PS		
0	59	83%
1	12	17%

Characteristic	Number (N=71)	Percent (%)
Clinical Stage		
cT2	56	79%
cT3	15	21%
AMVAC Cycles		
2	7	10%
3	64	90%
TRAE		
Grade 3/4	12	17%
Grade 5	1	1.4%

Results



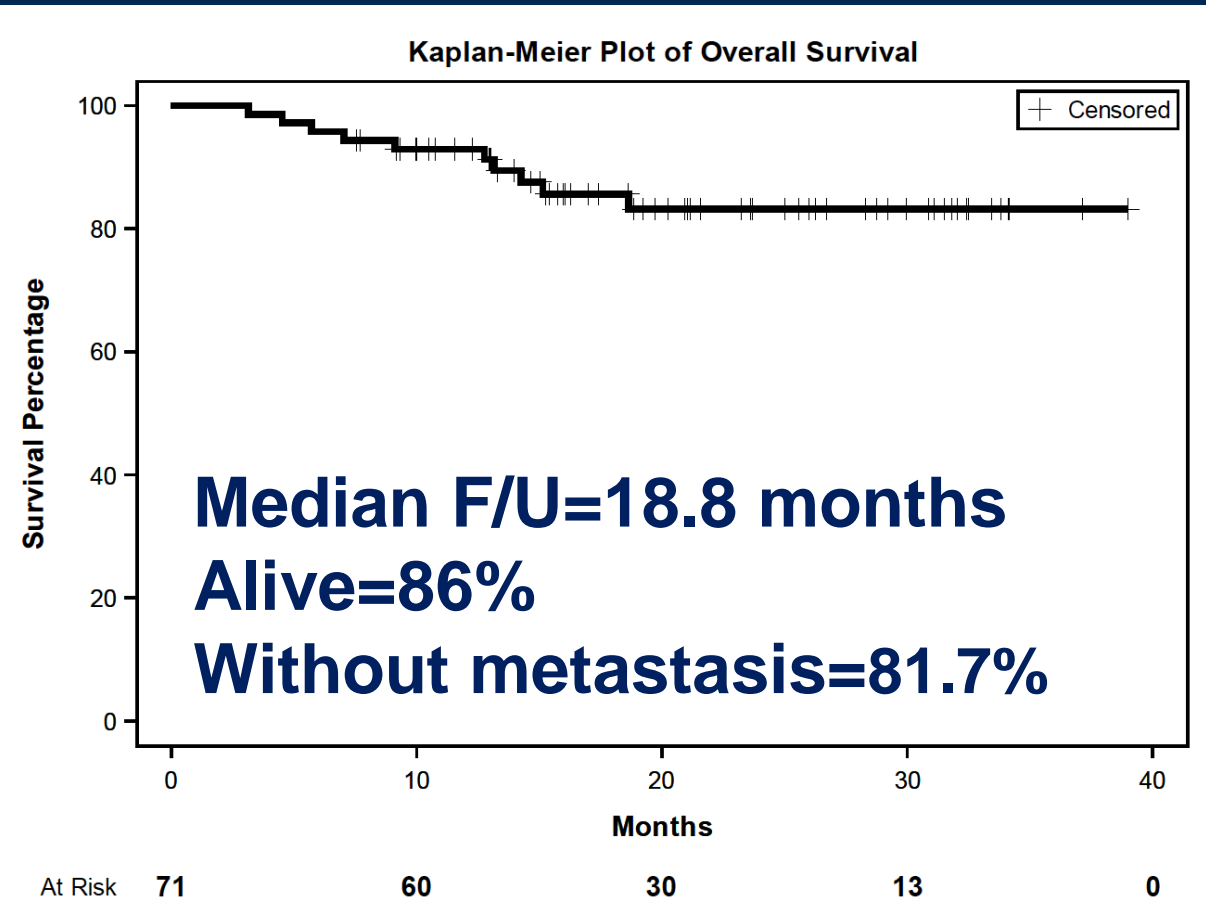
Results: Mutation Positive on Active Surveillance



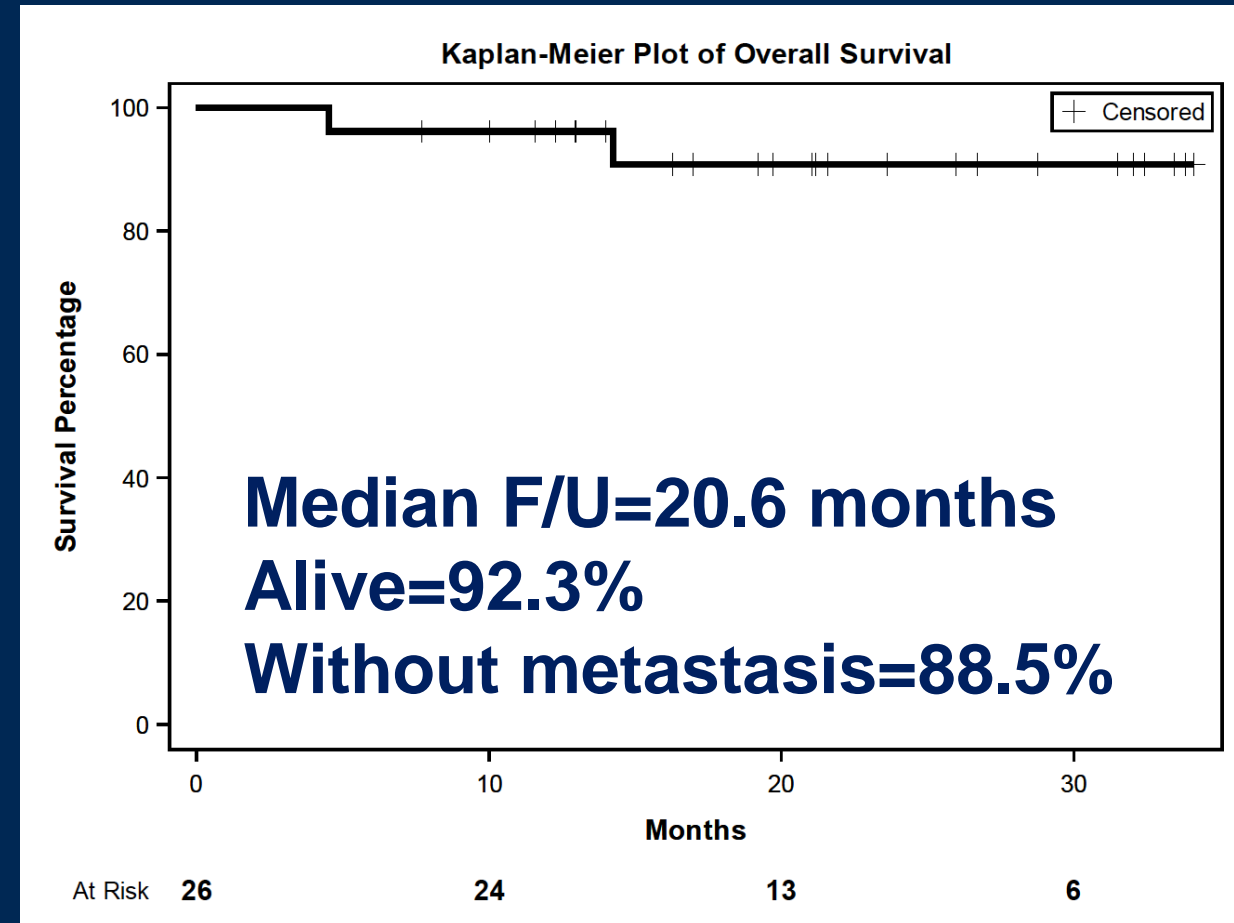
v=VUS; p=pathogenic; *=more than one mutation or variant; d=death

Results: Overall Survival

ITT (N=71)



Active Surveillance (N=26)



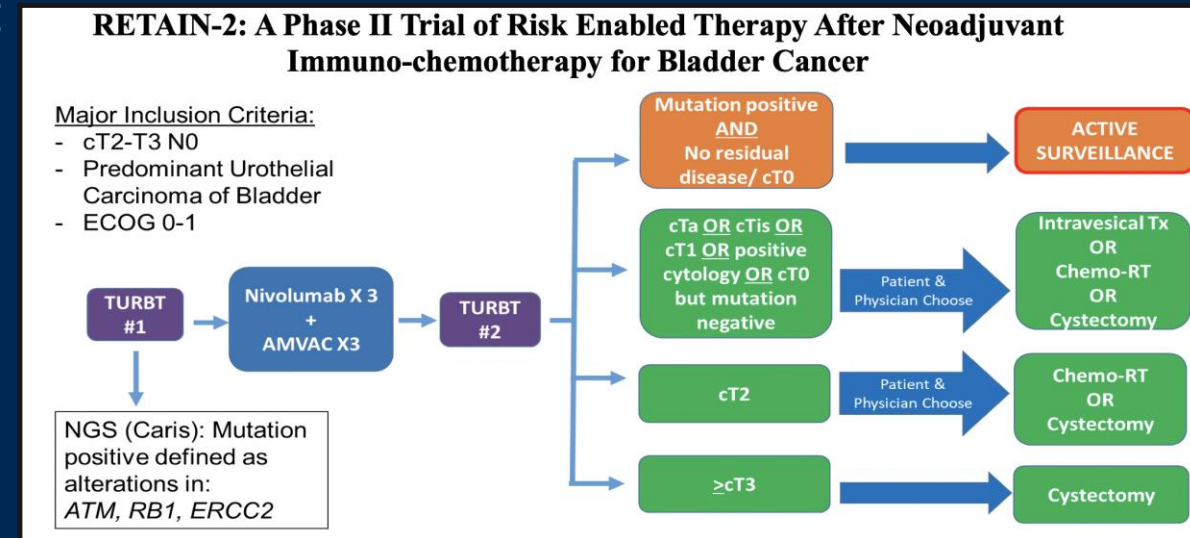
Results: Mutation distribution in surveillance patients

Total N=26	Patient Number (%)
<i>RB1</i>	13 (50%)
<i>ATM</i>	11 (42%)
<i>ERCC2</i>	8 (31%)
<i>FANCC</i>	1 (4%)
Multiple	7 (27%)

Total N=26	Recur (N=17)	Not Recur (N=9)
Pathologic mutation(s) present	8/17=47%	5/9=56%
VUS mutation(s) only	9/17=53%	4/9=44%
<i>ERCC2</i> present	3/17=18%	5/9=56%
<i>RB1</i> present	9/17=53%	4/9=44%
<i>ATM</i> present	7/17=41%	4/9=44%

Conclusions

- Follow-up continues for the primary endpoint of 2 year MFS in ITT: 81.7% are so far w/o M1 dz
- 77% of patients on active surveillance are alive, without M1 dz and with their bladder intact
- 65% of patients on active surveillance have had some form of recurrence:
 - 9/17 being NMIBC with bladder still intact
- 11.5% of patients on active surveillance have had M1 dz vs. 23.6% in those w/o mut.
- HCRN GU16-257 and A031701 are ongoing
- Risk adapted bladder preservation is NOT a standard-of-care



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Thank you

- Session Chair
 - Girish S. Kulkarni, MD, PhD
- Colleagues & Collaborators
 - TJU
 - MedStar
 - JHU
- Patients and Families

Fox Chase Cancer Center GU Team

