

# Considerations for Harmonizing Clinical Trial Conduct in Adjuvant Bladder and Kidney Cancer Trials: Inclusion Criteria and Disease Recurrence

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# Objectives

- Discuss eligibility criteria on adjuvant bladder and kidney cancer trials
- Discuss considerations in defining and managing disease recurrence on adjuvant bladder and kidney cancer trials
- Review common goals and methods for clinical trial conduct

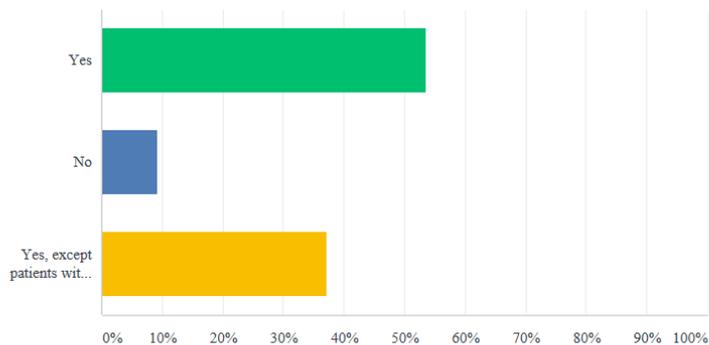
# Considerations for Inclusion Criteria on Adjuvant Trials



- Variant histology
- Positive margins
- Extent of surgery
- Exclusion criteria

## Should patients with variant histology be included on urothelial carcinoma trials?

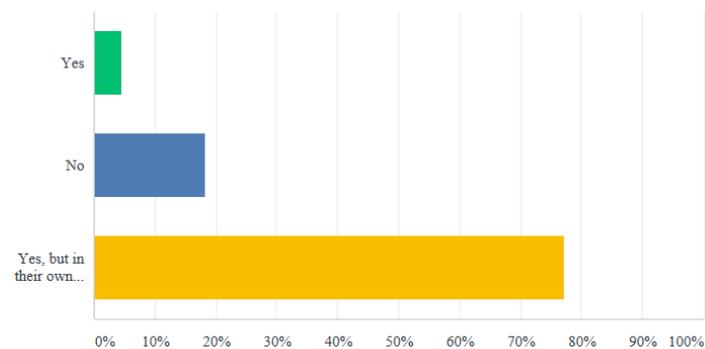
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ANSWER CHOICES	RESPONSES	
Yes	53.49%	23
No	9.30%	4
Yes, except patients with small cell bladder cancer	37.21%	16
<b>TOTAL</b>		<b>43</b>

## Should patients with non-clear cell histology be included on trial with patients that have clear cell histology?

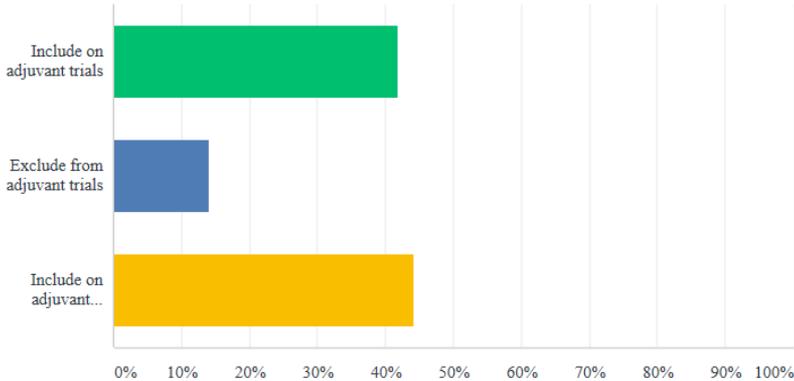
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ANSWER CHOICES	RESPONSES	
Yes	4.55%	2
No	18.18%	8
Yes, but in their own cohort	77.27%	34
<b>TOTAL</b>		<b>44</b>

## What do you think should be done about patients with positive margins after cystectomy?

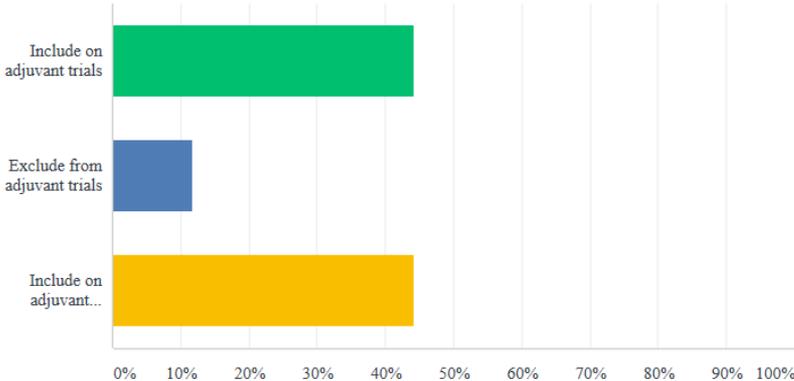
Answered: 43 Skipped: 2



ANSWER CHOICES	RESPONSES
Include on adjuvant trials	41.86% 18
Exclude from adjuvant trials	13.95% 6
Include on adjuvant trials, but in their own cohort	44.19% 19
<b>TOTAL</b>	<b>43</b>

## What do you think should be done about patients with positive margins after nephrectomy?

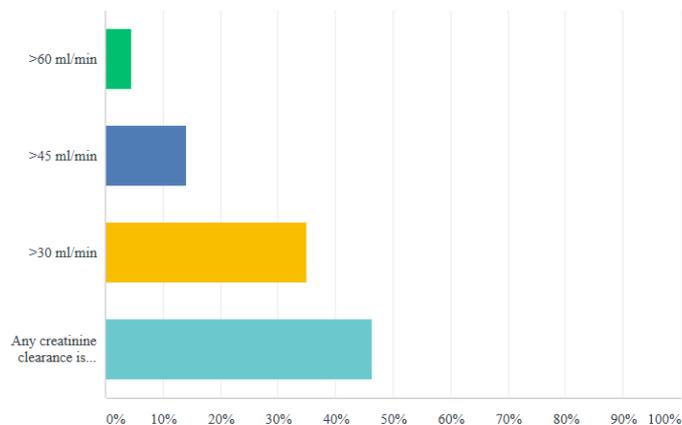
Answered: 43 Skipped: 2



ANSWER CHOICES	RESPONSES
Include on adjuvant trials	44.19% 19
Exclude from adjuvant trials	11.63% 5
Include on adjuvant trials, but in their own cohort	44.19% 19
<b>TOTAL</b>	<b>43</b>

## What Creatinine Clearance cut-off do you think is most appropriate for immunotherapy trials in adjuvant Urothelial Cancer?

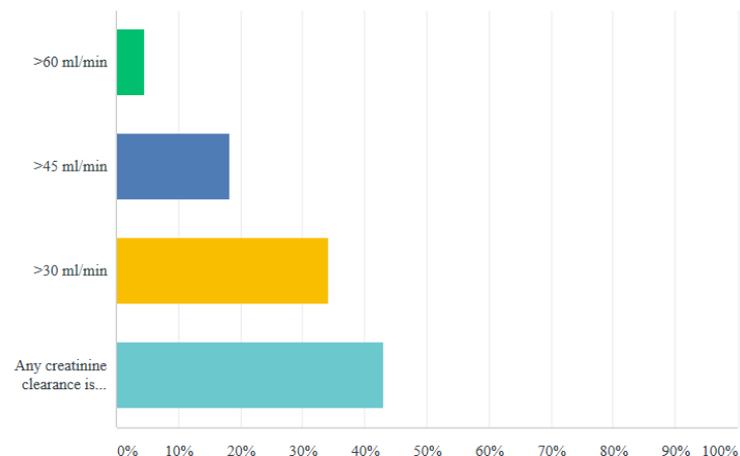
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ANSWER CHOICES	RESPONSES	
>60 ml/min	4.65%	2
>45 ml/min	13.95%	6
>30 ml/min	34.88%	15
Any creatinine clearance is acceptable in this patient population	46.51%	20
<b>TOTAL</b>		<b>43</b>

## What Creatinine Clearance cut-off do you think is most appropriate for immunotherapy trials in adjuvant RCC?

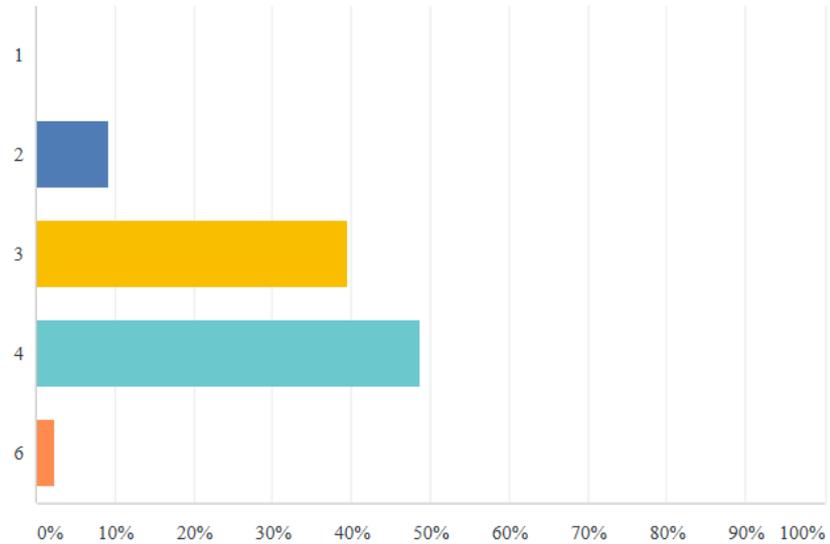
Answered: 44 Skipped: 1



ANSWER CHOICES	RESPONSES	
>60 ml/min	4.55%	2
>45 ml/min	18.18%	8
>30 ml/min	34.09%	15
Any creatinine clearance is acceptable in this patient population	43.18%	19
<b>TOTAL</b>		<b>44</b>

# How many cycles do you think constitutes adequate neoadjuvant treatment for Urothelial Cancer?

Answered: 43 Skipped: 2



ANSWER CHOICES	RESPONSES	
1	0.00%	0
2	9.30%	4
3	39.53%	17
4	48.84%	21
6	2.33%	1
<b>TOTAL</b>		<b>43</b>

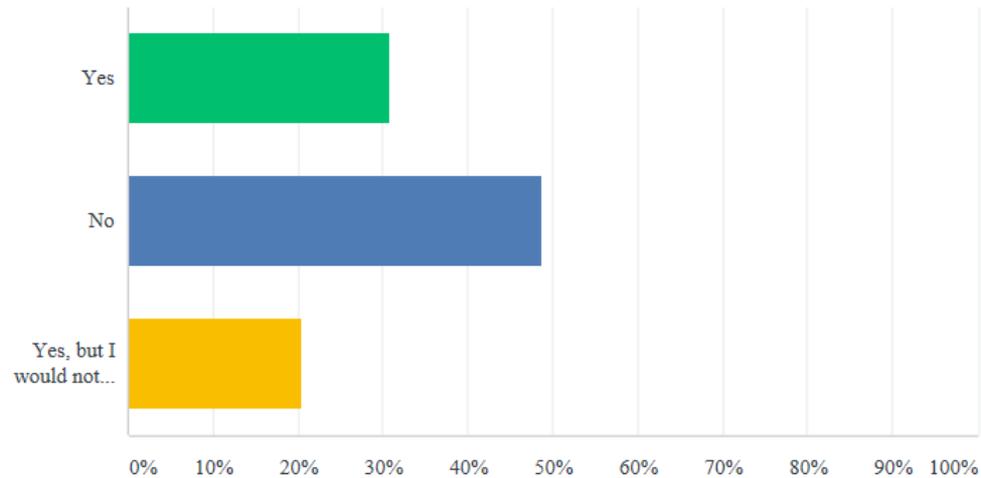
# Considerations for Managing NMIBC on Adjuvant Bladder Trials



- Development of NMIBC on an adjuvant study
- Administering BCG while patient is on an experimental treatment
- Monitoring patients

# Would you administer BCG for NMIBC in a patient who is also receiving an experimental treatment on an adjuvant urothelial cancer trial?

Answered: 39 Skipped: 6



ANSWER CHOICES	RESPONSES	
Yes	30.77%	12
No	48.72%	19
Yes, but I would not combine it with immunotherapy agents	20.51%	8
TOTAL		39

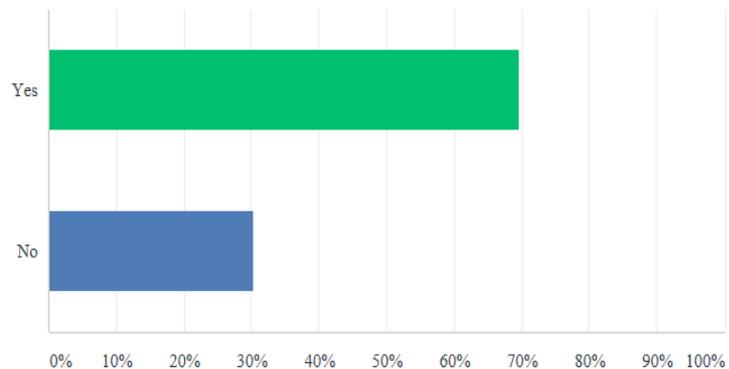
# The Definition of Disease Recurrence



- Consideration of:
  - Entry criteria for indeterminate lesions
  - Definitions of recurrence for RCC trials
  - The role of biopsy in determining recurrence
  - Work up for equivocal or indeterminate findings

## Do you think IV contrast is essential to identify baseline disease in bladder and kidney cancer?

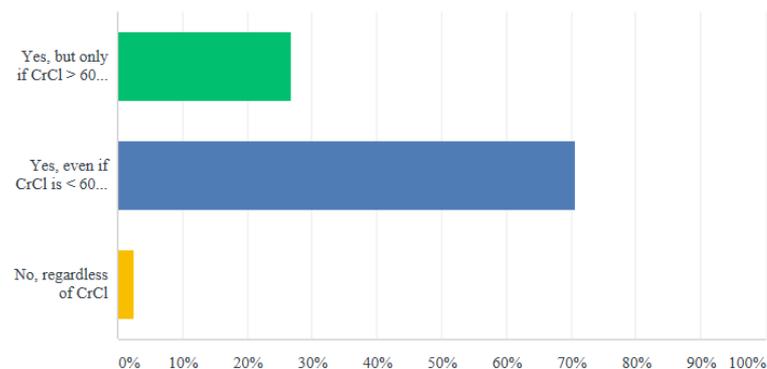
Answered: 43 Skipped: 2



ANSWER CHOICES	RESPONSES
Yes	69.77% 30
No	30.23% 13
TOTAL	43

## Do you feel comfortable administering IV contrast to a kidney cancer patient s/p nephrectomy for baseline imaging?

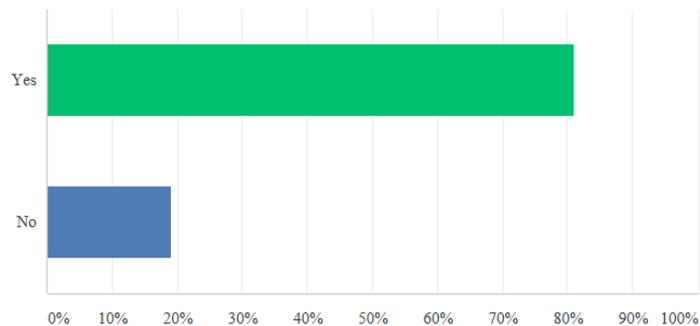
Answered: 41 Skipped: 4



ANSWER CHOICES	RESPONSES
Yes, but only if CrCl > 60 ml/min	26.83% 11
Yes, even if CrCl is < 60 ml/min but adequate per my institution's guidelines	70.73% 29
No, regardless of CrCl	2.44% 1
TOTAL	41

## Should all suspected urothelial cancer recurrences be biopsied if safe/feasible?

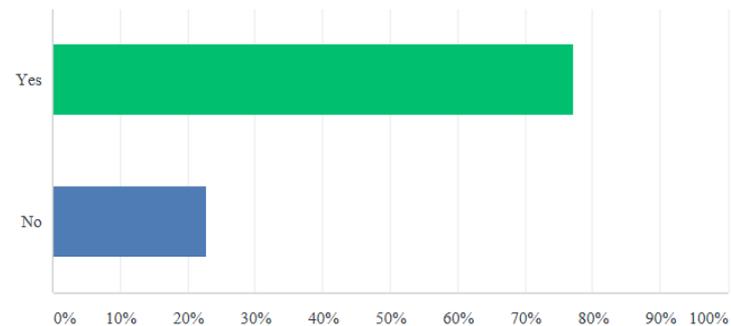
Answered: 42 Skipped: 3



ANSWER CHOICES	RESPONSES	
Yes	80.95%	34
No	19.05%	8
TOTAL		42

## Should all suspected RCC recurrences be biopsied in safe/feasible?

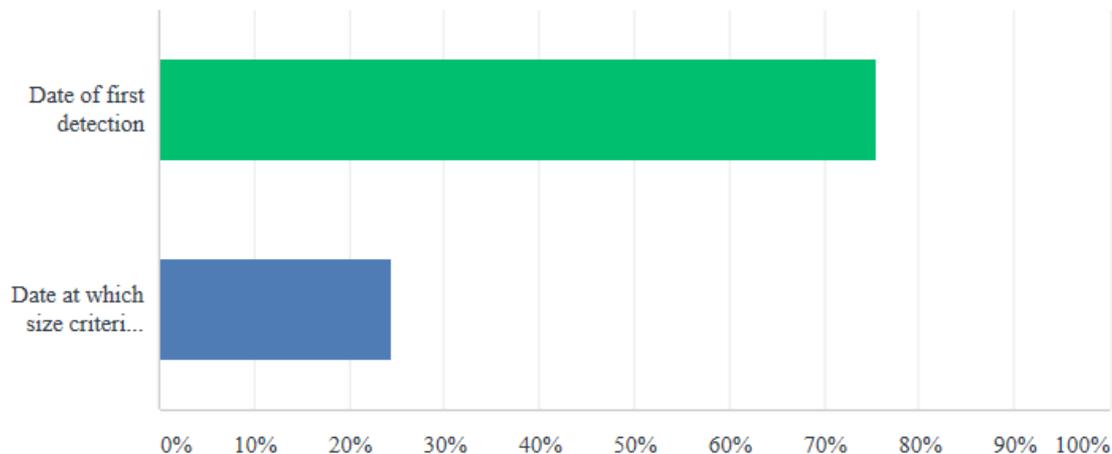
Answered: 44 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	77.27%	34
No	22.73%	10
TOTAL		44

Which date should represent the DFS date for trial if serial CT scans are done to confirm growth of a suspected recurrence in bladder OR kidney cancer?

Answered: 45 Skipped: 0



ANSWER CHOICES	RESPONSES	
Date of first detection	75.56%	34
Date at which size criteria for recurrence was met	24.44%	11
TOTAL		45

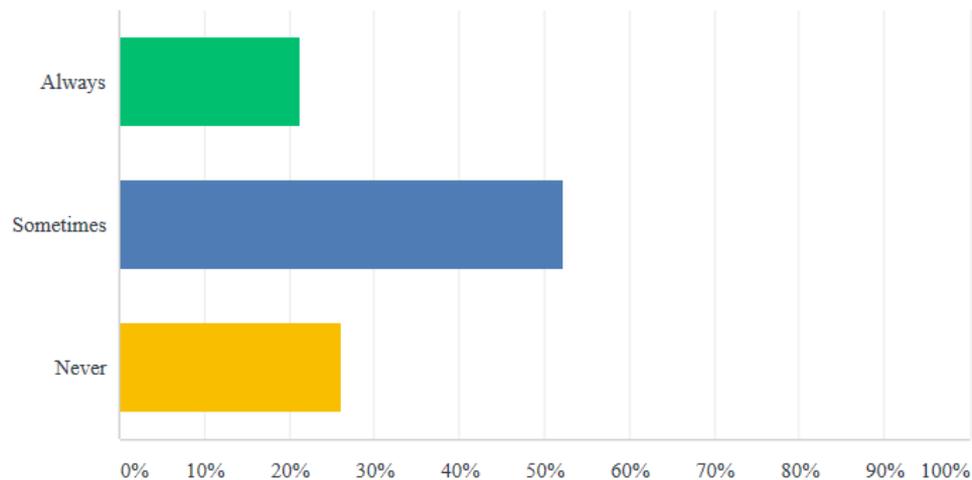
# The Patient Experience



- Patient input and experience necessary to goals
- Patient advocates on each panel
- Opportunities for comments and Q&A

# How often do you reference Patient Reported Outcomes data from a clinical trial when discussing risk/benefit of treatment with patients?

Answered: 42 Skipped: 3



ANSWER CHOICES	RESPONSES	
Always	21.43%	9
Sometimes	52.38%	22
Never	26.19%	11
<b>TOTAL</b>		<b>42</b>

# Structure of the Workshop

- Speaker(s) will frame discussion
- Panel to discuss the data and gaps in data
- Each session followed by time for audience Q&A and comments
- Lunch 12-12:45

# Overall Goals



- Inform the GU community of the current state of the science
- Allow for expert opinion and potential consensus in areas where data is lacking
- Allow for public commentary