

MasterClass in Bladder Cancer 2026

Discussion with a clinical case

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Organized by:
HENDERE HEALTHCARE

 [#BladderMasterClass26](#)

 Hospital Universitario
12 de Octubre



Disclosures

None

Case report



55-year-old, male, never smoker

Medical history:

Dyslipidemia

Urological history:

Right **nephroureterectomy** with bladder cuff (3 years ago): Urothelial carcinoma **pT3G3N0**

Single Mitomicine dose after catheter removal

Adjuvant therapy: 4 cycles of **Carboplatin-Gemcitabine** IV



Follow up

Cystoscopy: 2cm bladder recurrence

Cytology: Positive

TURBT: T1G3HG with healthy muscularis

Additional clinical risk factors are*:

- o age > 70;
- o multiple papillary tumours;
- o tumour diameter $\geq$ 3 cm.

Risk group	
Low Risk	• A primary, single, TaT1 LG/G1 tumour < 3 cm in diameter without CIS in a patient $\leq$ 70 years
	• A primary Ta LG/G1 tumour without CIS with at most ONE of the additional clinical risk factors (see above*)
Intermediate Risk	Patients without CIS who are not included in either the low-, high-, or very high-risk groups
High Risk	• <u>All T1 HG/G3 without CIS, EXCEPT</u> those included in the very high-risk group
	• All CIS patients, EXCEPT those included in the very high-risk group
	Stage, grade with additional clinical risk factors: • Ta LG/G2 or T1G1, no CIS with all 3 risk factors • Ta HG/G3 or T1 LG, no CIS with at least 2 risk factors • T1G2 no CIS with at least 1 risk factor
Very High Risk	Stage, grade with additional clinical risk factors: • Ta HG/G3 and CIS with all 3 risk factors • T1G2 and CIS with at least 2 risk factors • T1 HG/G3 and CIS with at least 1 risk factor • T1 HG/G3 no CIS with all 3 risk factors

NMIBC risk calculator

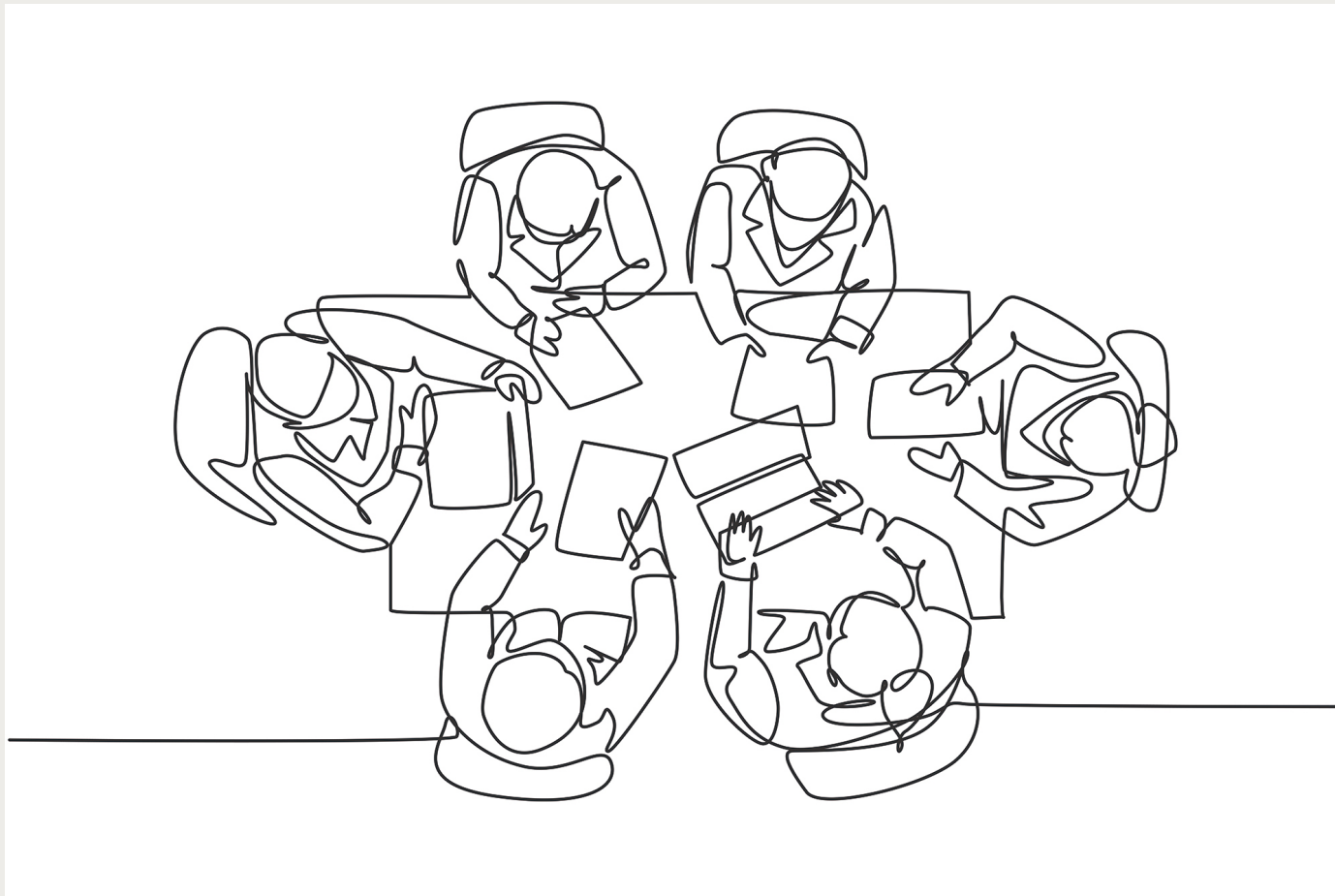
Resultados

Probabilidad de progresión después de RTUV sin
inducción o mantenimiento de BCG

	BASADO EN OMS 2004/2016 Alto Riesgo	BASADO EN OMS 1973 Alto Riesgo
a 1 año	3.5%, 2.4%-5.2%	3.8%, 2.6%-5.7%
a los 5 años	9.6%, 7.4%-12%	11%, 8.1%-14%
a los 10 años	14%, 11%-18%	14%, 10%-19%

Probabilidad de progresión e intervalo de confianza del 95%

Discussion



Perform a second TURB in the following situations: • after incomplete initial TURB, or in case of doubt about completeness of a TURB; • if there is no detrusor muscle in the specimen after initial resection, with the exception of Ta LG/G1 tumours and primary CIS; • in <u>T1 tumours</u>.	Strong
If indicated, perform a second TURB <u>within 2–6 weeks</u> after the initial resection. This second TURB should include resection of the primary tumour site.	Weak

Take biopsies from abnormal-looking urothelium. <u>Biopsies from normal-looking mucosa</u> (mapping biopsies from the trigone, bladder dome, right, left, anterior and posterior bladder wall) are recommended if <u>cytology or urinary molecular marker test is positive</u> . If the equipment is available, perform fluorescence-guided (PDD) biopsies.	Strong
Take a <u>biopsy of the prostatic urethra</u> in cases of bladder neck tumour, if bladder carcinoma <i>in situ</i> is present or suspected, if there is <u>positive cytology</u> or urinary molecular marker test without evidence of tumour in the bladder, or if abnormalities of the prostatic urethra are visible. If biopsy is not performed during the initial procedure, it should be completed at the time of the second resection.	Strong
Take a <u>prostatic urethral biopsy</u> from the pre-collicular area (between the 5 and 7 o'clock position) <u>using a resection loop</u> . In case any abnormal-looking areas in the prostatic urethra are present at this time, these need to be biopsied as well.	Weak



2nd TURBT

Resection of the previous scar: TaG3HG

CIS in 2 random biopsies

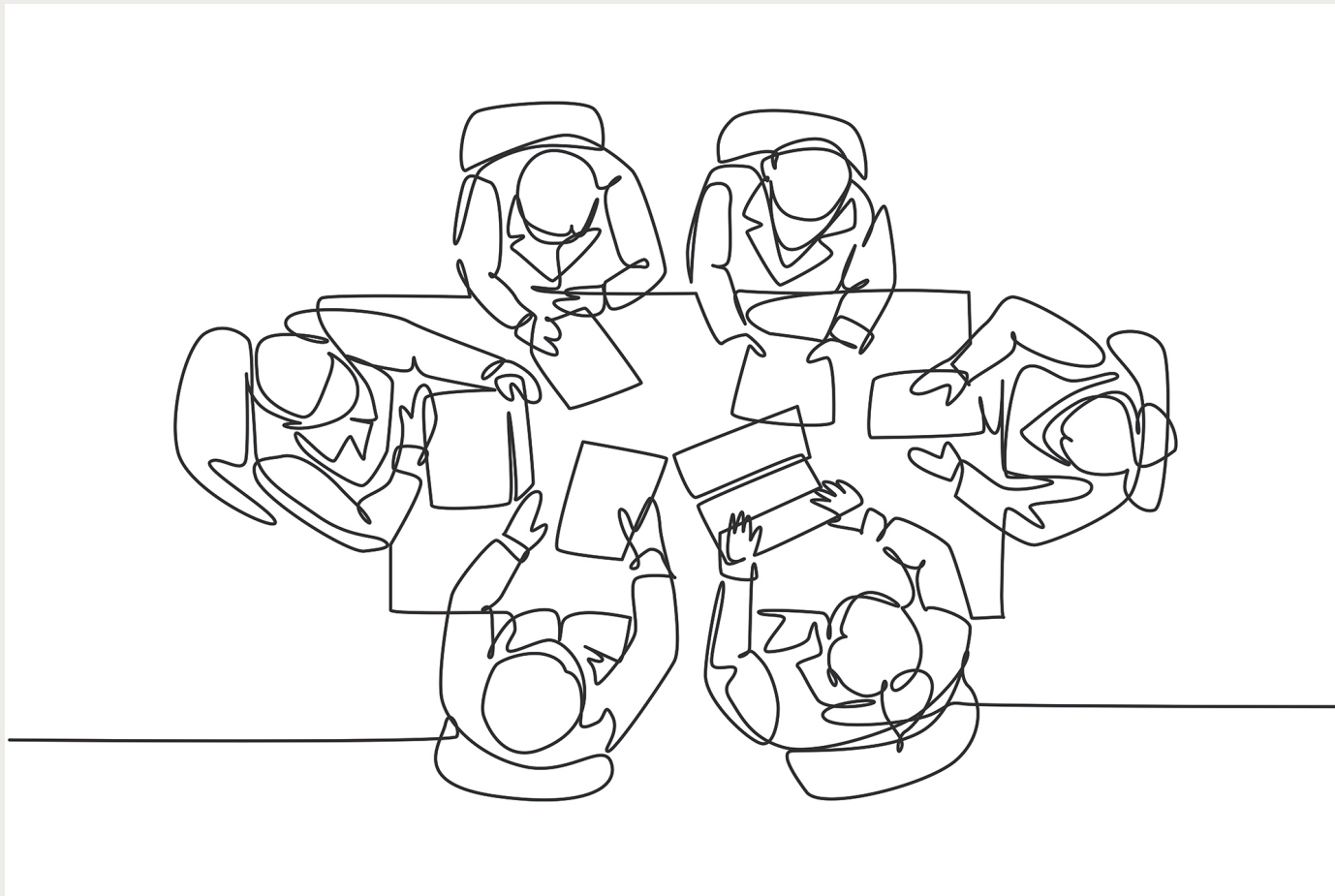
Negative prostatic
urethra biopsy

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	• A primary Ta LG/G1 tumour without CIS with at most ONE of the additional clinical risk factors (see above*)
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High Risk	• All T1 HG/G3 without CIS, EXCEPT those included in the very high-risk group
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Additional clinical risk factors are*:

- o age > 70;
- o multiple papillary tumours;
- o tumour diameter ≥ 3 cm.

Discussion



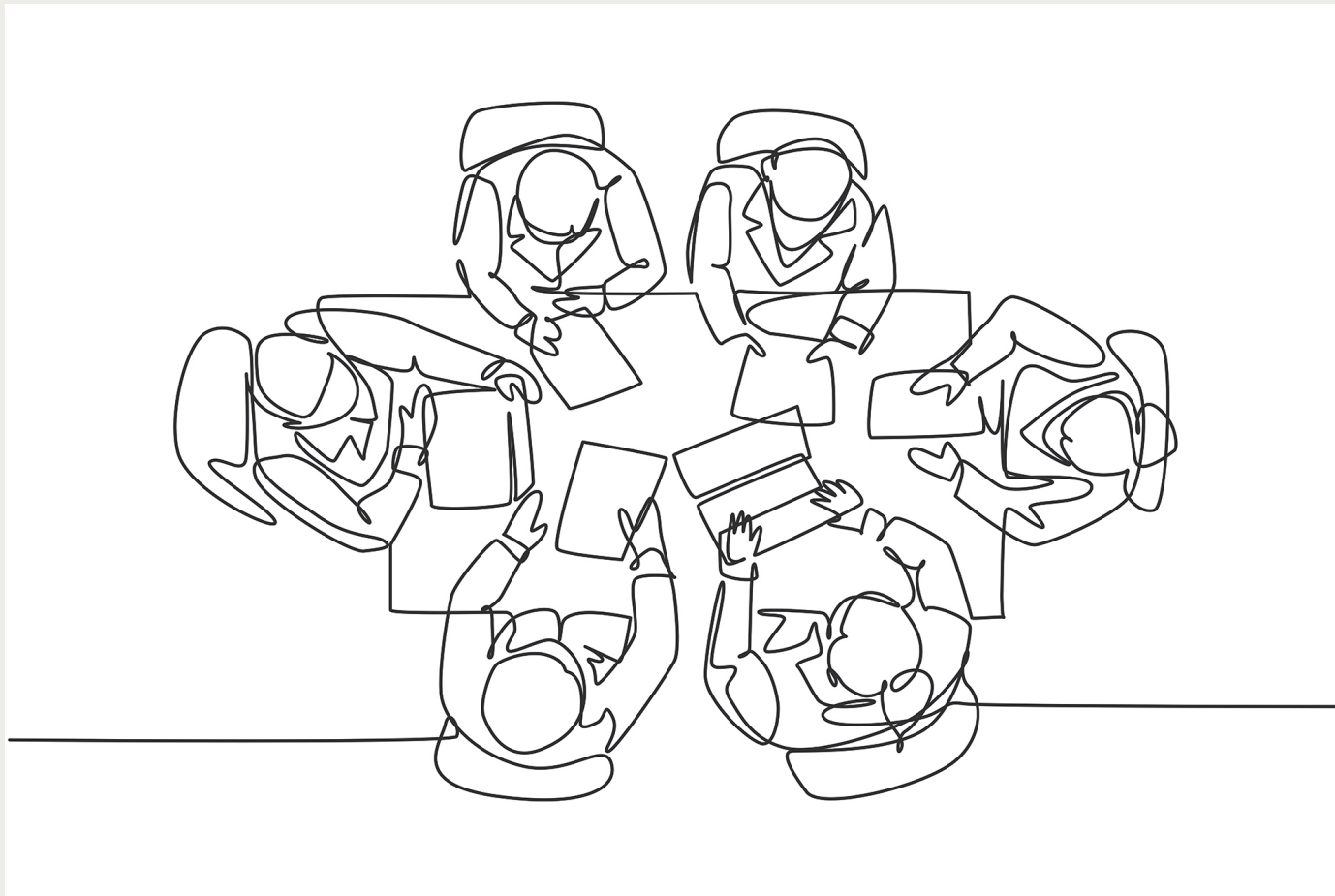


Adjuvant treatment at this point

T1G3 + CIS, solitary 2cm bladder tumor

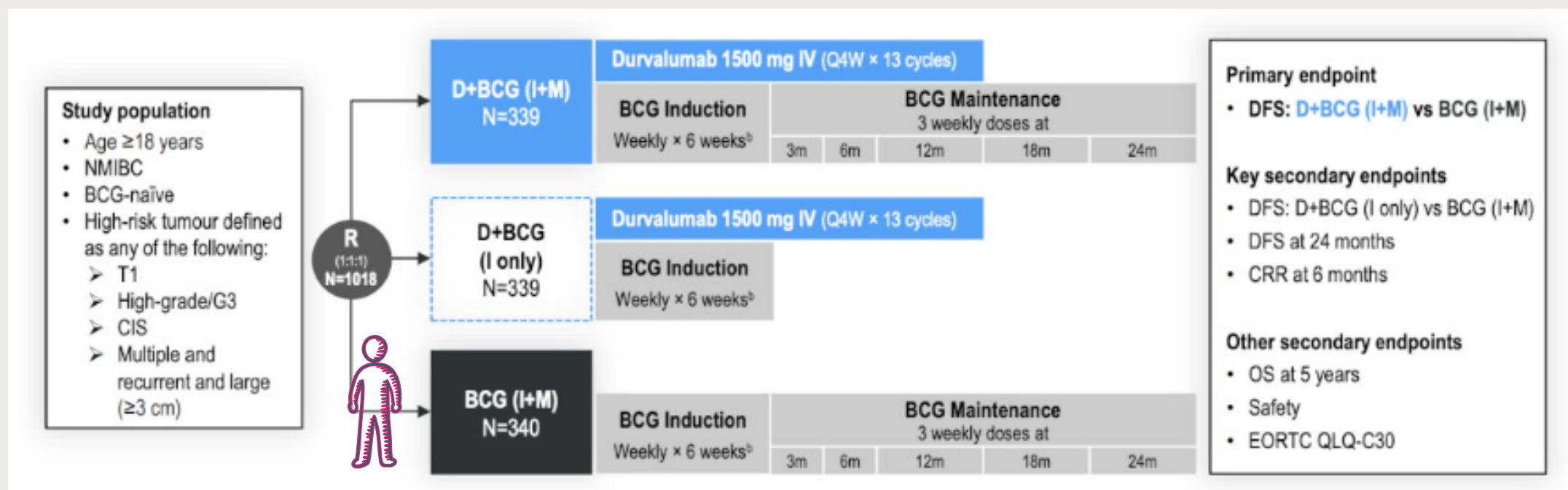
- Chemohyperthermia (HIVEC)
- Gemcitabine/Docetaxel
- BCG 1 year
- BCG 3 years
- BCG naïve Clinical Trial

Discussion



Inclusion BCG naïve Clinical Trial

POTOMAC





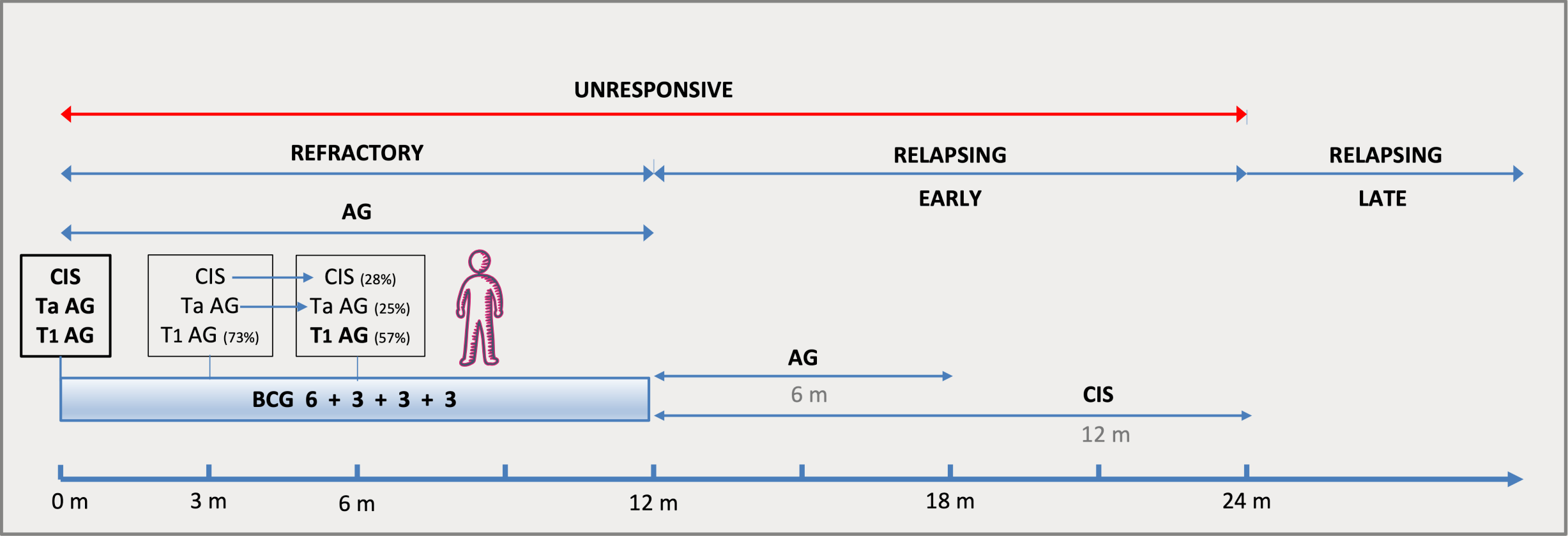
Follow up

After 6 BCG induction doses + 3 maintenance doses

Recurrence: 1cm, solitary bladder tumor; TaG3HG + CIS

*** Adequate BCG is defined as the completion of at least 5 of 6 doses of an initial induction course plus at least 2 out of 6 doses of a second induction course or 2 out of 3 doses of maintenance therapy.*

BCG unresponsive



BCG Refractory ≈ Early relapsing (1)
BCG Refractory peor pronóstico que Late relapsing (1) (2)
() Probabilidad de progresión

(1) Can Urol Assoc 2020;14(6):204
(2) Herr. Urol Oncol 2015;33:108e 1-4

FDA approvals for BCG unresponsive

2021

FDA approves pembrolizumab for BCG-unresponsive, high-risk non-muscle invasive bladder cancer

CR 41% AAT
CR 19% 12m

2022

FDA D.I.S.C.O. Burst Edition: FDA approves Adstiladrin (nadofaragene firadenone) for patients with high-risk Bacillus Calmette-Guérin unresponsive non-muscle invasive bladder cancer with carcinoma in situ or without papillary lesions

CR 53.4% AAT
CR 30% 12m

2024

FDA approves enfortumab vedotin alfa inbakicept-pmln for BCG-unresponsive non-muscle invasive bladder cancer

CR 71% AAT
CR 43% 12m

2025

FDA approves gemcitabine intravesical system for non-muscle invasive bladder cancer

CR 82.4% AAT
CR 45.9% 12m

EXCLUSIVELY CIS



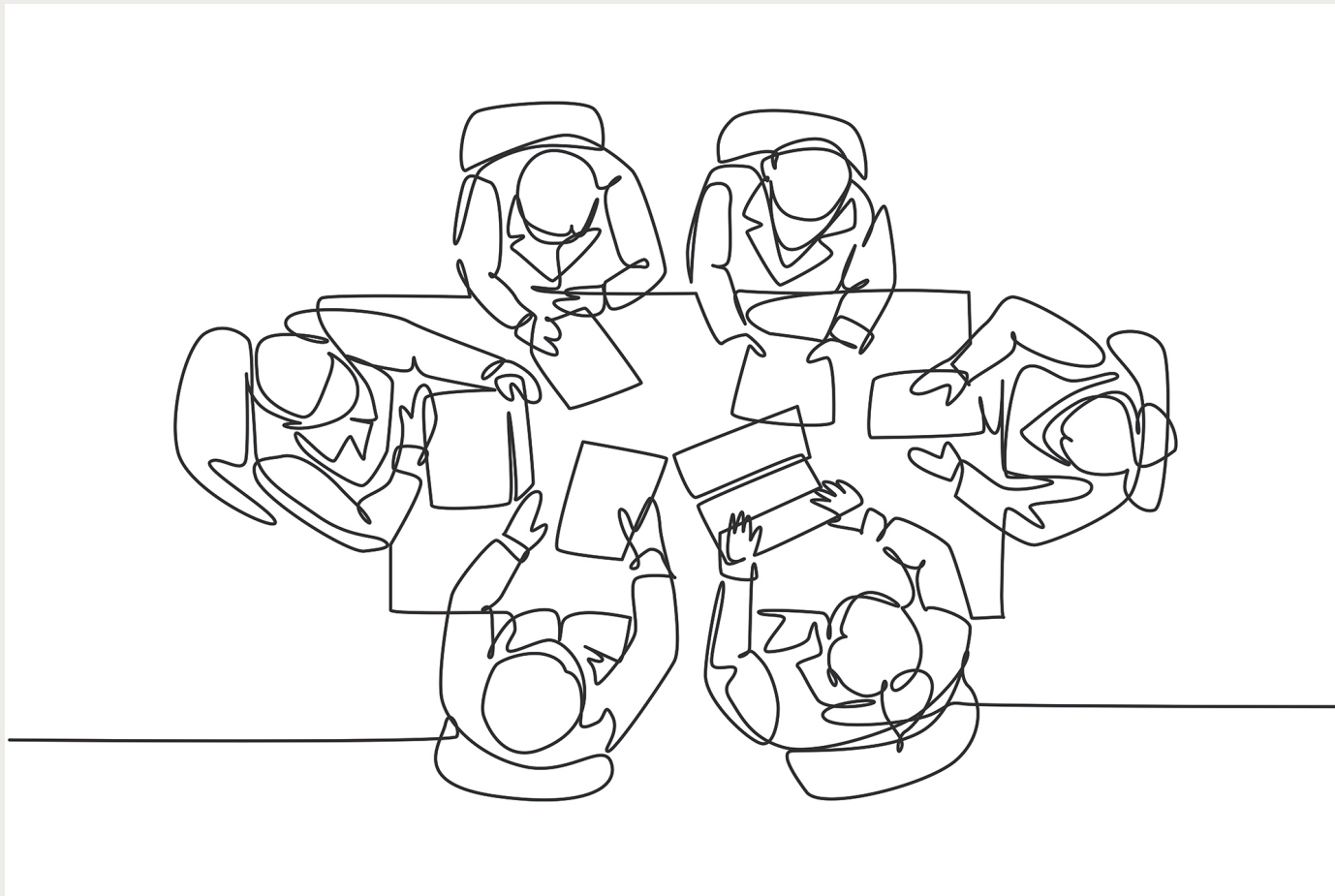
What do we do now?

First talk about radical cystectomy: Patient **refuses**

No EMA approvals

We try inclusion in several clinical trials: **Excluded** due to upper urinary tract carcinoma history

Discussion

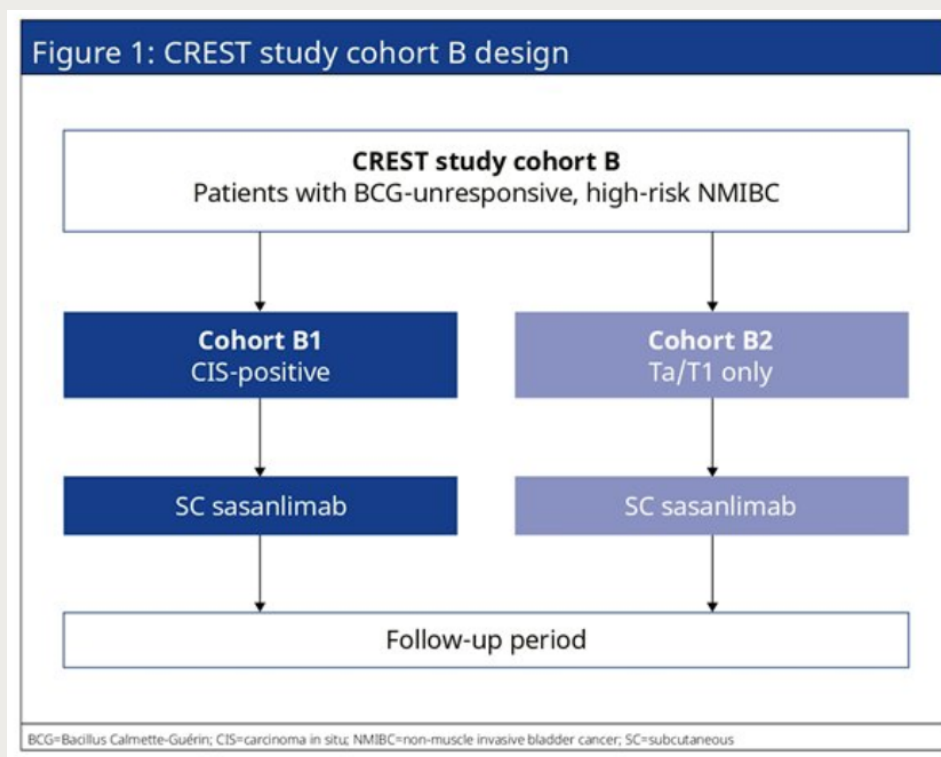




Last minute call!

We get a positive response from a CT sponsor!

CREST (Cohort B): Sasanlimab s.c. 600mg/42 days for 2 years





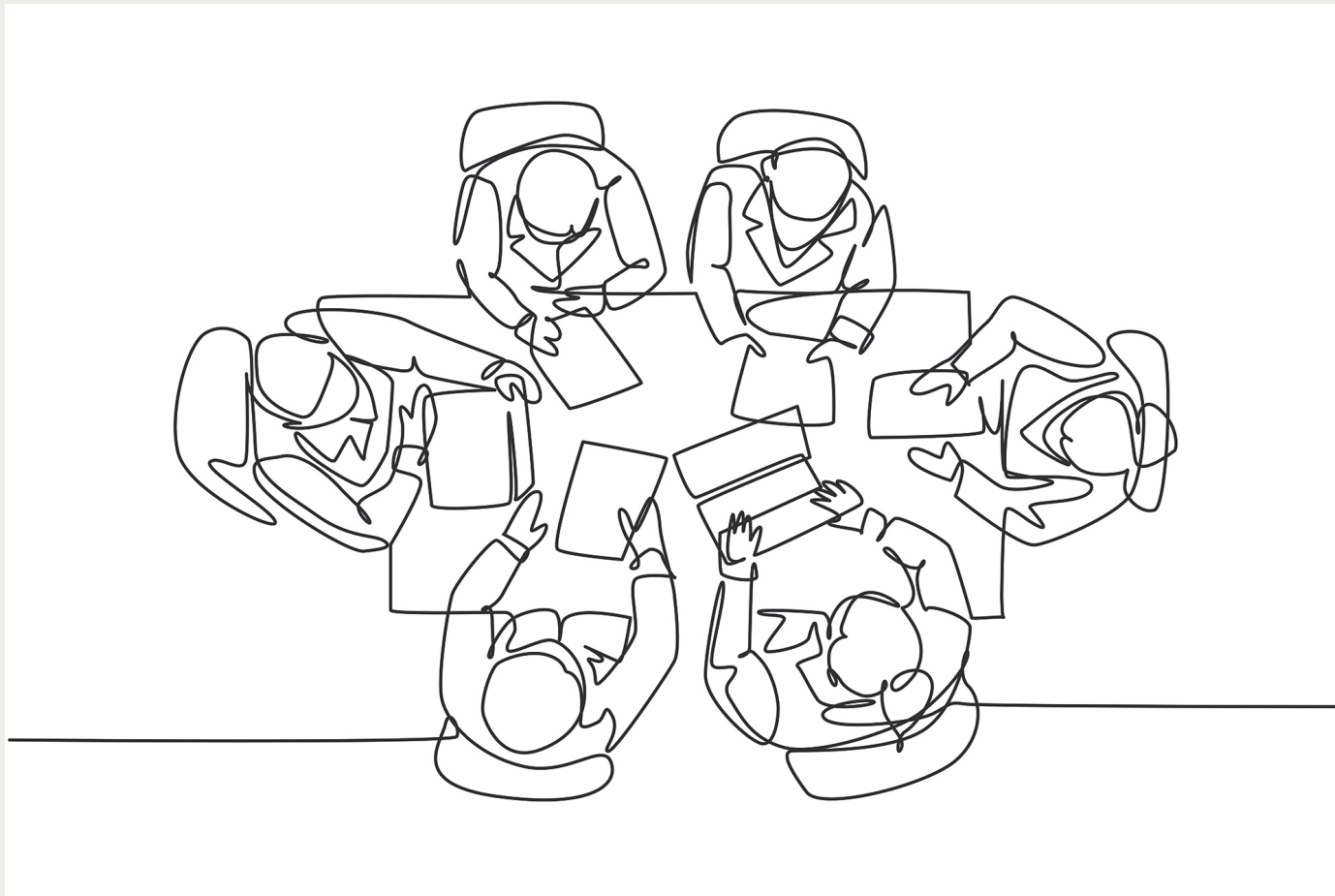
Follow up

7 months and 5 sasanlimab doses later

Recurrence: Multiple subcentimetric lesions; TaG3HG + CIS

Don't want to hear about a radical cystectomy

Discussion



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¡Gracias!

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 Hospital Universitario
SaludMedica 12 de Octubre

