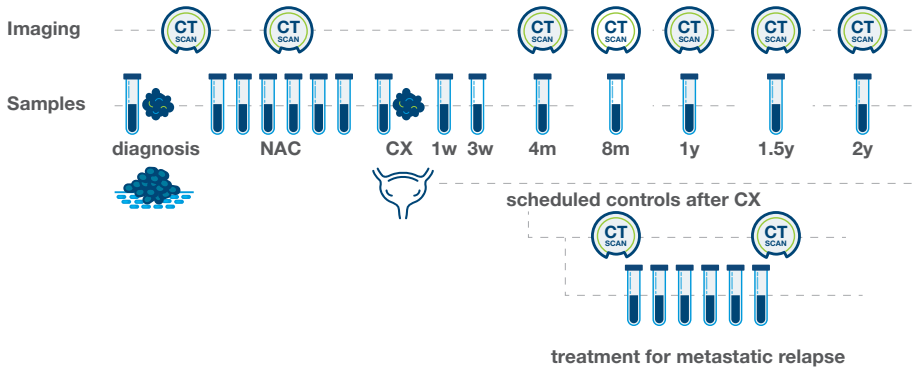
Christensen et al published in *Journal of Clinical Oncology*

Signatera ctDNA in muscle invasive bladder cancer: stronger predictive factor than lymph node status

Aarhus University study overview

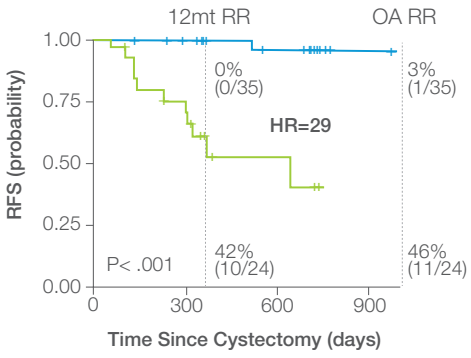
- **68 patients** with muscle-invasive bladder cancer (MIBC) treated with neoadjuvant chemotherapy and radical cystectomy, followed by surveillance
- **656 plasma samples** longitudinally collected before, during, and after therapy and analyzed retrospectively using Signatera



Neoadjuvant setting: lack of ctDNA clearance during neoadjuvant treatment is a better predictor of recurrence than pathologic response

Single timepoint before neoadjuvant chemo

Recurrence Free Survival (RFS)

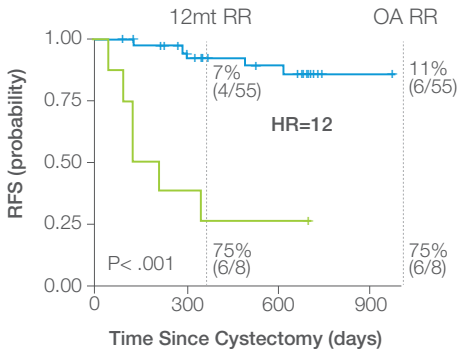


No. at risk

Negative	35	32	23	1
Positive	24	16	4	0

Single timepoint after completion of neoadjuvant chemo

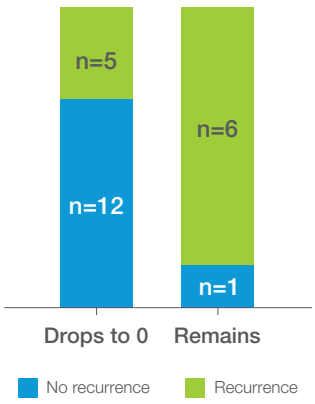
Recurrence Free Survival (RFS)



No. at risk

Negative	55	49	28	1
Positive	8	3	2	0

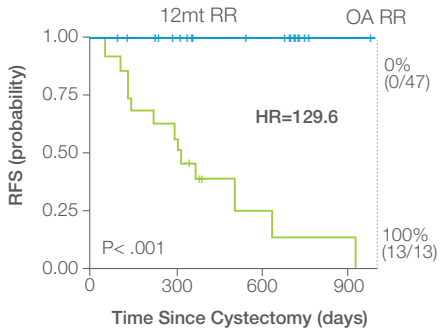
ctDNA associated with response to neoadjuvant chemotherapy



Surveillance: Longitudinal ctDNA status after cystectomy predictive of relapse with 96 day median lead time

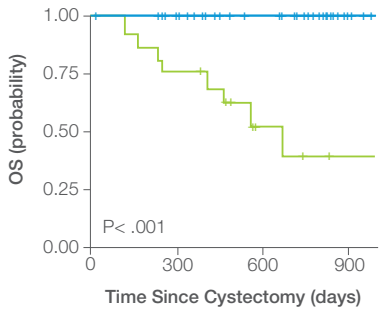
Longitudinal testing after cystectomy

Recurrence Free Survival (RFS)



No. at risk				
Negative	47	42	29	1
Positive	17	11	2	1

Overall Survival (OS)



No. at risk				
Negative	48	45	32	22
Positive	18	14	7	2

- ctDNA is a stronger predictive factor than lymph node status or pathologic staging
- Sensitivity = 100%
- Specificity = 98%
- Highly prognostic with RFS HR=129.6
- Lead time to clinical recurrence of median 96 days
- Patients with serial negative ctDNA after cystectomy had 100% OS

How can Signatera support patient care decisions?

- ctDNA testing may inform the benefit of escalating surveillance imaging
- Persistent ctDNA negativity may be associated with markedly improved outcomes without adjuvant therapy

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Price Transparency Program (PTP) with Compassionate Care – personalized cost estimates, self-pay cash option, and access to affordable testing for patients experiencing financial hardship

Flexible phlebotomy options – via local, Natera-approved lab or at-home mobile phlebotomy services; available in all states, at no cost to patients

References

Christensen E, Birkenkamp-Demtröder K, Sethi H, et al. Early detection of metastatic relapse and monitoring of therapeutic efficacy by ultra-deep sequencing of plasma cell-free DNA in patients with urothelial bladder carcinoma. J Clin Oncol. 2019;37(18):1547-1557. doi:10.1200/ JCO.18.02052

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The test described has been developed and its performance characteristics determined by the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US Food and Drug Administration (FDA). Although FDA is exercising enforcement discretion of premarket review and other regulations for laboratory-developed tests in the US, certification of the laboratory is required under CLIA to ensure the quality and validity of the tests. CAP accredited, ISO 13485 certified, and CLIA certified. © 2021 Natera, Inc. All Rights Reserved.

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