

Natera Inc.

Oncology call

October 10, 2019

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Conceive. Deliver. Thrive.

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Our telephone number is (650) 249-9090.

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Signatera success to date

- ✓ Published validation studies in 4 cancer types (Nature, JAMA Oncology, etc.)
- ✓ Completion of 2 additional studies (pan-cancer monitoring and neoadjuvant breast)
- ✓ FDA breakthrough status
- ✓ ~25 biopharma partnerships
- ✓ $50 million partnership with BGI
- ✓ Draft Medicare local coverage decision in colorectal cancer
- ✓ Partnership with Foundation Medicine

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Agenda

- Signatera overview
- Data presented to date
- Key commercial pathways:
  - ✓ Direct pharma channel
  - ✓ Direct clinical channel
  - ✓ Partnership in China with BGI Genomics
  - ✓ Partnership with Foundation Medicine

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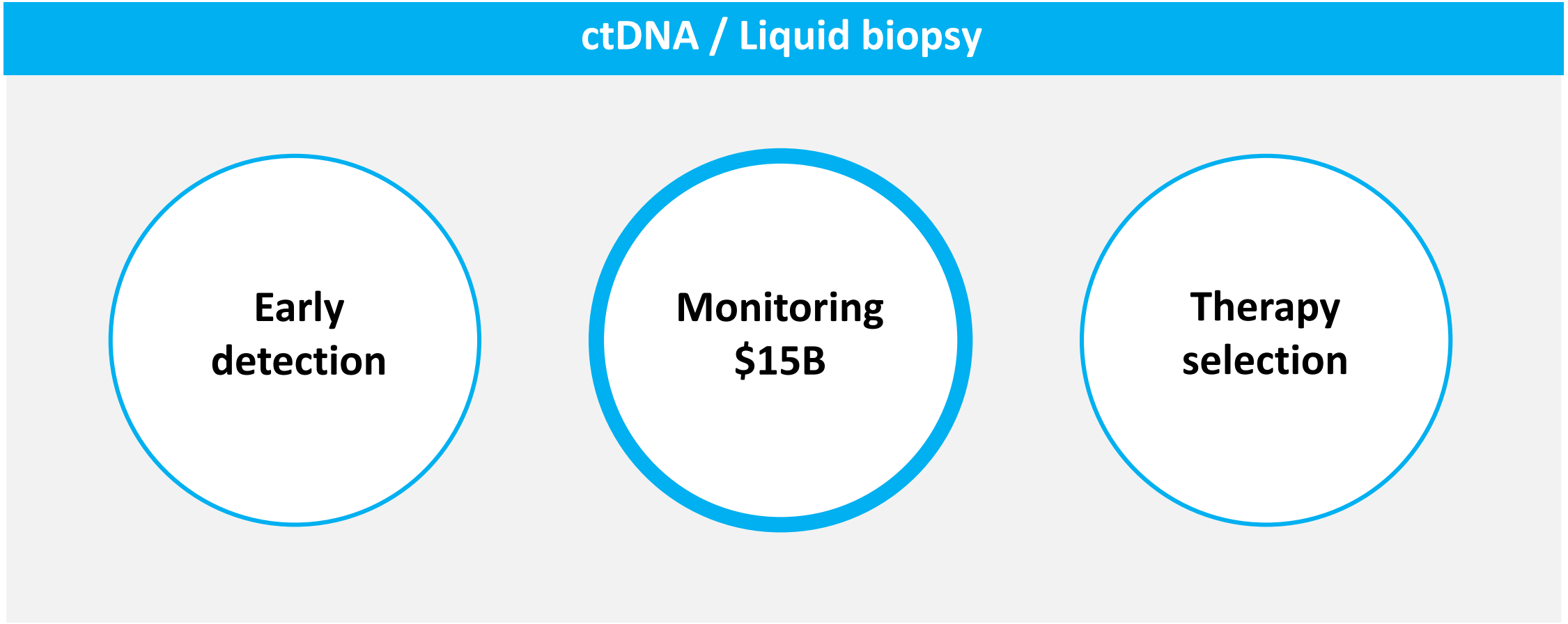
Oncology MRD market opportunity



Based on internal company estimates

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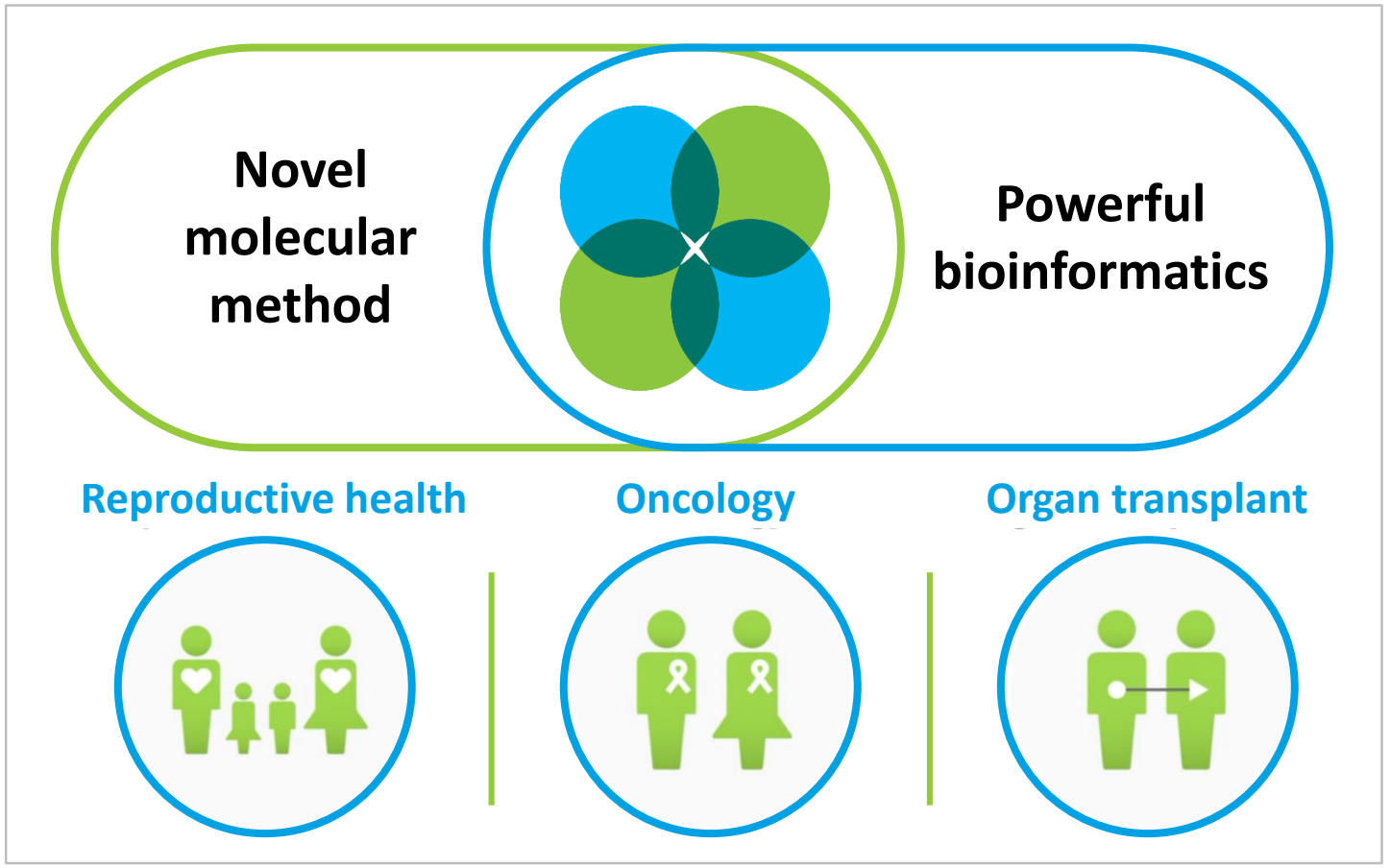
Natera’s technology designed to analyze cell-free DNA

- 10+ years of experience with cell free DNA
- >2 million tests performed
- Single molecule sensitivity in a tube of blood



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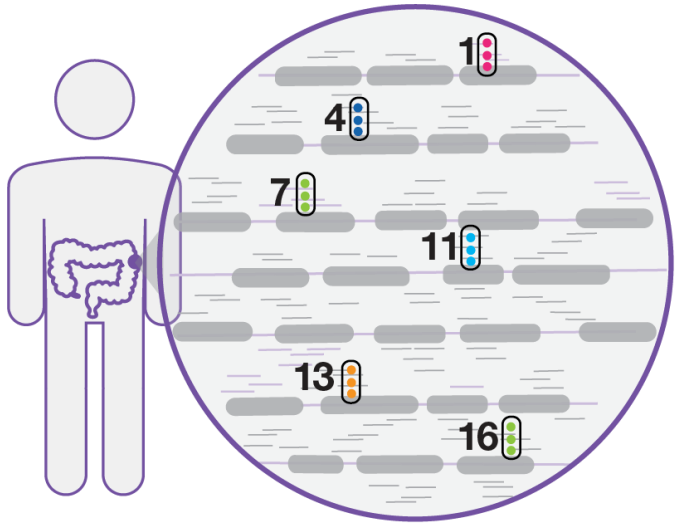
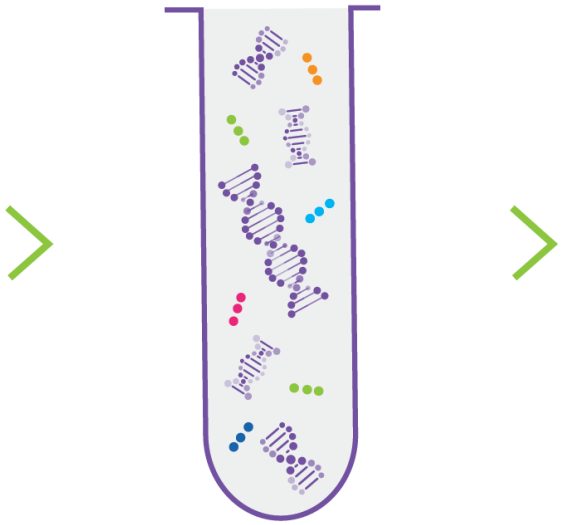
How Signatera works

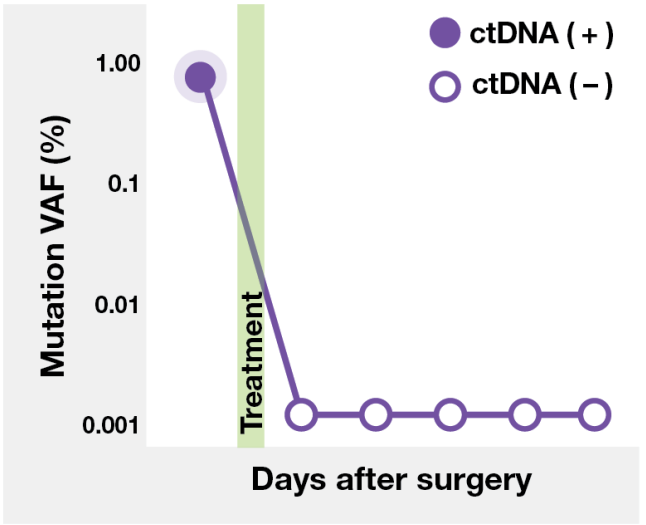
Sequencing of tumor tissue, to identify unique signature of tumor mutations

Custom design and manufacture of personalized mPCR assay for each patient, targeting the top 16 clonal mutations found in tumor

Use personalized assay to test patient's blood for presence of circulating tumor DNA (ctDNA)







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Why personalized and tumor-informed?

Requirements for effective monitoring and MRD assessment	Personalized, tumor-informed
1 Ultra-sensitive detection of small traces of tumor DNA	✓ Enough variants to track ✓ Ultra-deep sequencing at >100,000X NGS coverage
2 Accurate measurement of disease burden (ctDNA quantity)	✓ Measure only clonal mutations, reflective of full disease burden
3 Cost-efficient for frequent repeat testing	✓ Only sequence tumor-derived variants – no wasted sequencing

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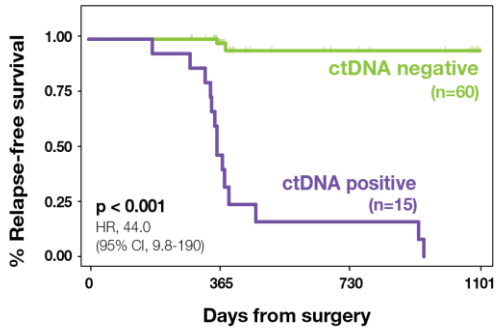
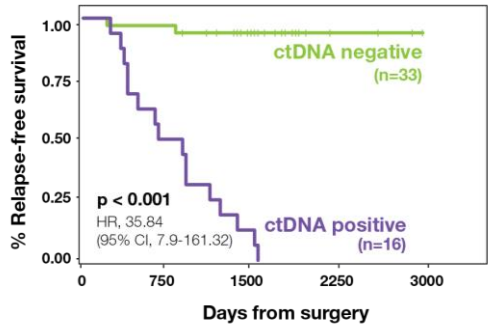
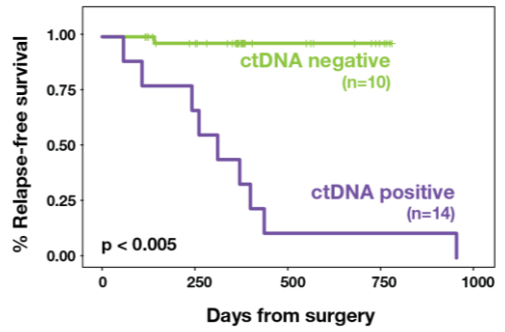
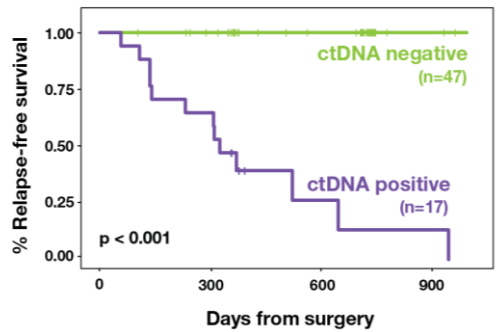
Signatera validated across multiple tumor types

JAMA Oncology	Clinical Cancer Research	Nature	Journal of Clinical Oncology
Colon[1]	**Breast[2]**	**Lung[3]**	**Bladder[4]**
			
88% sensitivity to relapse Average lead time 8.7 mos	89% sensitivity to relapse Average lead time 9.5 mos	92% sensitivity to relapse Average lead time 4.0 mos	100% sensitivity to relapse Average lead time 2.8 mos

Positive Signatera result, without further treatment, has predicted relapse with overall PPV > 98%[1-4]

1. Reinert T, Henriksen TV, Christensen E, et al.[AMA Oncol. 2019. doi:10.1001/jamaoncol.2019.0528. 2. Coombes RC, Page K, Salari R, et al. Clin Cancer Res. 2019. doi: 10.1158/1078-0432.CCR-18-3663. 3. Abbosh C, Birkbak NJ, Wilson GA, et al. Phylogenetic ctDNA analysis depicts early-stage lung cancer evolution. Nature. 2017;545:446-451. 4. Christensen E, Birkenskamp-Demtroder K, Sethi H, et al. J Clin Oncol. 2019. doi: 10.1200/JCO.18.02052.

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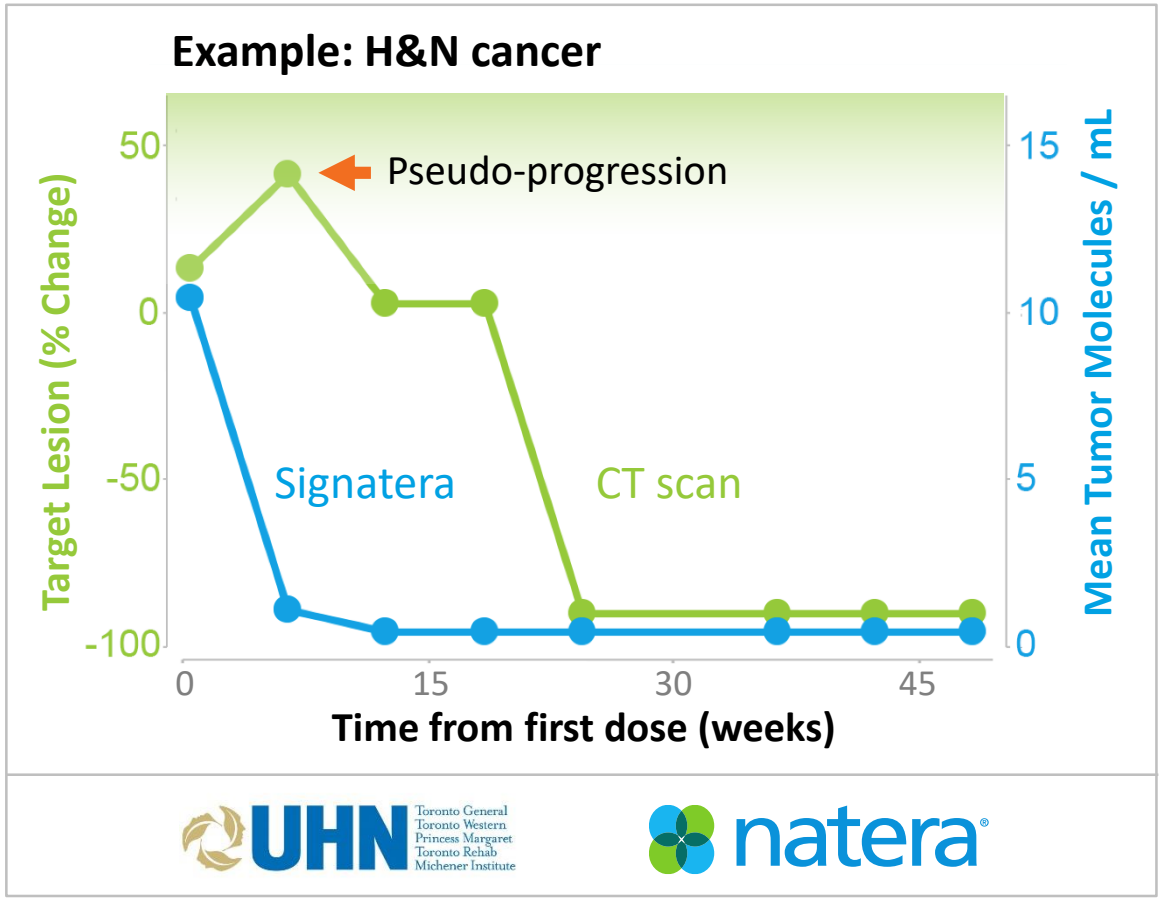
Signatera outperforms CT imaging for evaluating response to Keytruda immunotherapy

Current standard of care	Therapy response evaluated every 6-12 weeks with CT imaging
Complication	Up to *1 in 10 patients* experience pseudo-progression on imaging[2]
Solution	Signatera not fooled by pseudo-progression. Better, earlier measure of response.



UHN Toronto General Toronto Western Princess Margaret Toronto Rehab Michener Institute

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1. IQVIA Institute. Global Oncology Trends 2019. Therapeutics, clinical development and health system implications. Published May 2019.
2. Patel V. Progress on pseudoprogression. ddPCR for ctDNA could distinguish pseudoprogression from true disease progression. The pathologist. Published May 11, 2018.
3. Yang et al, ESMO 2019. Bespoke ctDNA Analysis as a Predictive Biomarker in Solid Tumor Patients Treated with Single-Agent Pembrolizumab.

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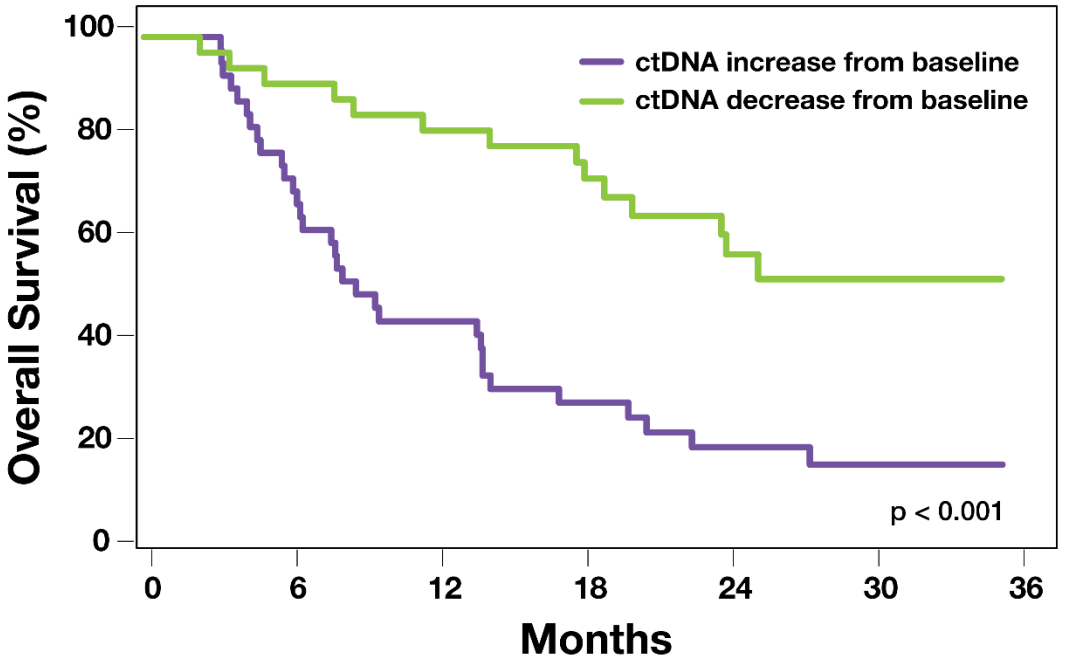
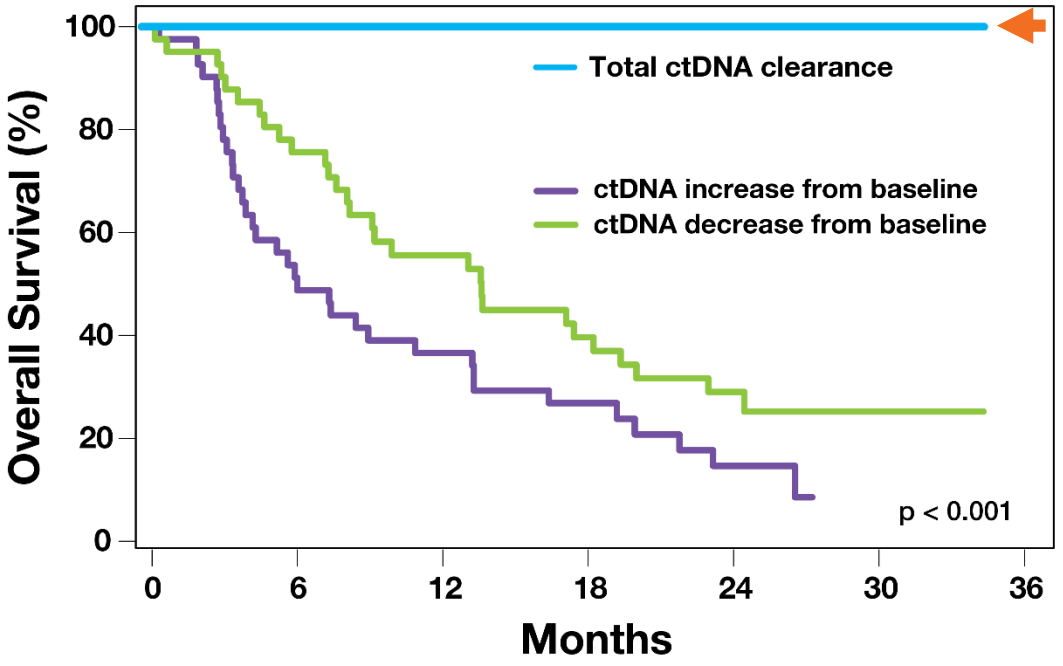
ctDNA changes predict outcomes

ctDNA decrease at 6 weeks correlates with 2x higher survival*



ctDNA clearance at any time during treatment correlates with 100% survival*



*Survivals are during the follow up period

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Key commercial channels

	FOUNDATION MEDICINE®	Direct channel Clinical	Direct channel Pharma	BGI
Presence	100K+ clinical patients/yr 50+ active pharma partners	Hiring oncology focused sales reps	Pharma BD reps	1 million+ genetic tests/yr in China
Application	Cancer monitoring	Stage II-III CRC, more to come	Study enrichment, Treat on recurrence, Surrogate endpoint	Offer Signatera in China
Near term goal	Launch to biopharma in 2020	Final LCD in CRC, Drive clinical volumes	Grow contracted value and revenue	Launch in 2020

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Direct pharma channel strategy

Indications:

- Trial enrichment
- Treatment on molecular recurrence
- Tracking neoantigens
- Therapy effectiveness monitoring



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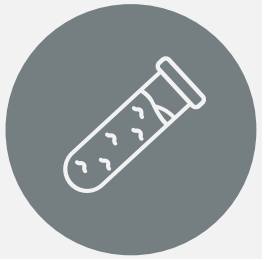
$50M oncology-focused partnership with BGI

Benefits to Natera



$35 million upfront[1]
$15 million milestones[2]



Ongoing royalties on sales



Signatera™ distribution in China

1. $35 million upfront to Natera. $6 million prepayment to BGI for sequencing services
2. Delivered upon achievement of key milestones

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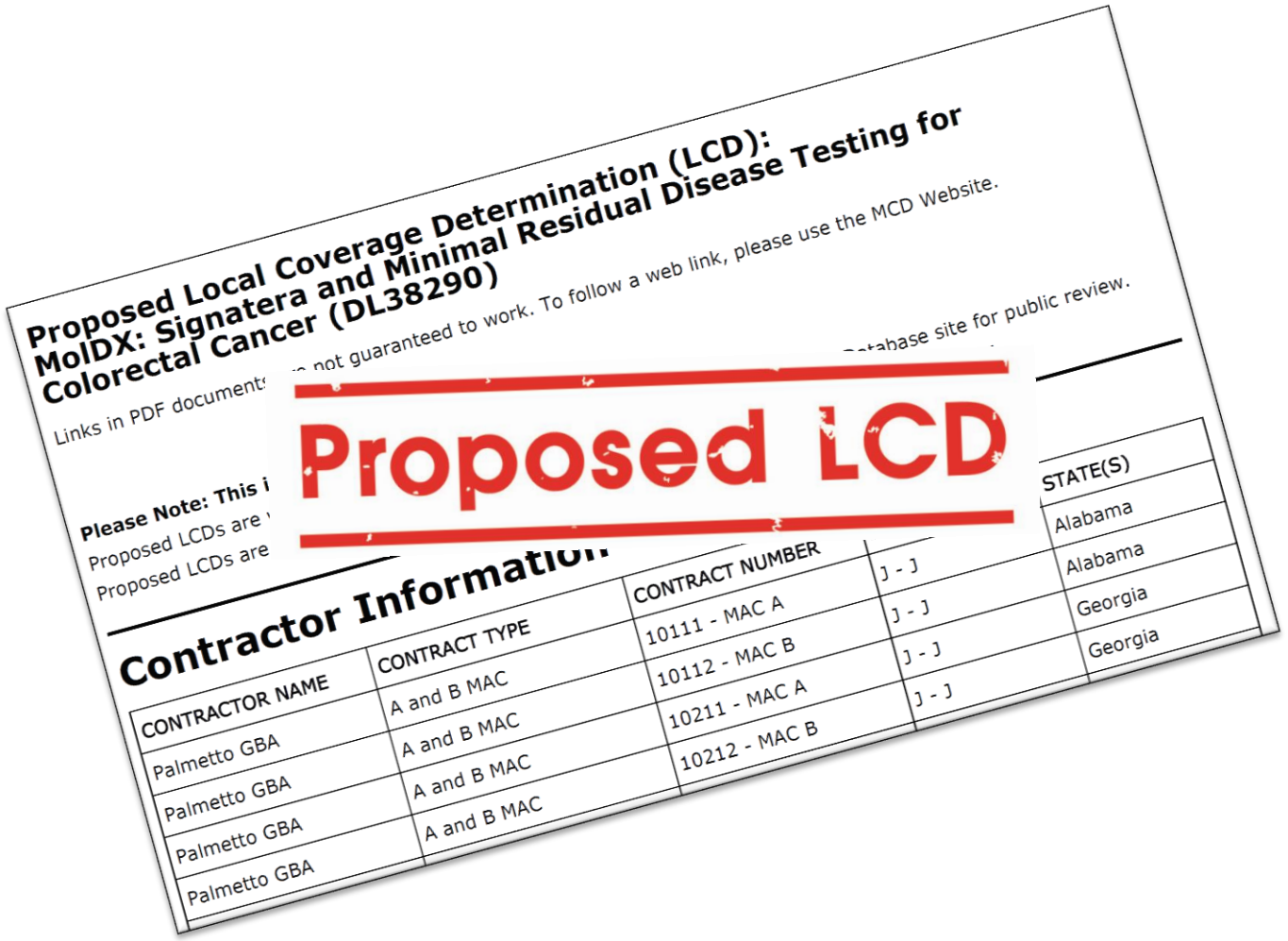
CMS issues draft local coverage in CRC

- Stage II – III colorectal cancer
- Estimated > 1MM tests per year
- Use case mirrors CEA testing currently in NCCN guidelines



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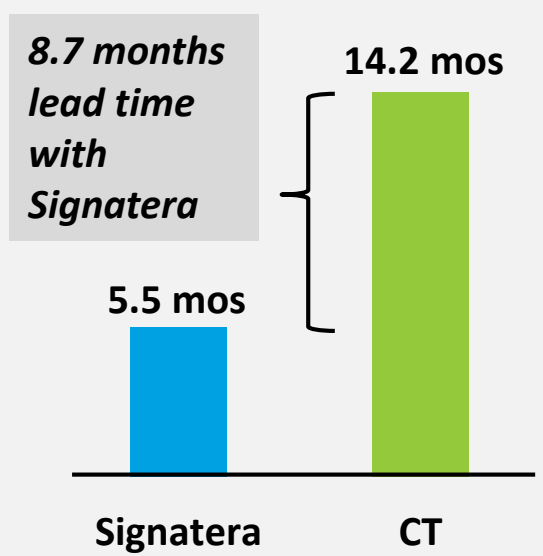
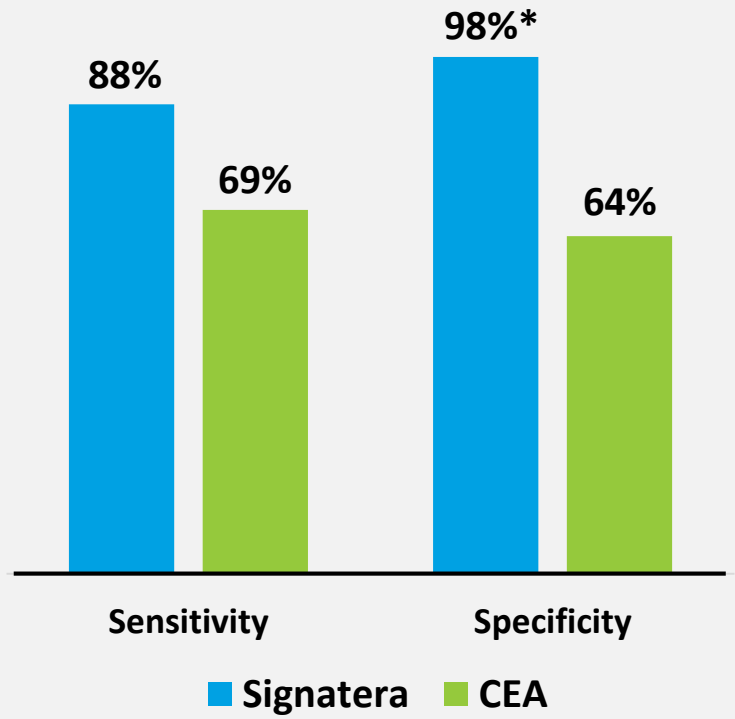
Unmet need #1 in CRC: Effective monitoring for relapse

- 25-30% of patients relapse[1,2]
- Over 85% of relapses caught **too late** for curative surgery[1,2]
- Signatera accuracy much higher than CEA
  - Signatera test-level specificity 99.7%[3]
  - Signatera PPV 97%

Avg time to relapse (months)[4]



Serial testing to detect relapse[4]



*Patient-level specificity 98%; test-level specificity 99.7%

1. Purandare NC, et al. The Indian journal of radiology & imaging. 2010;20(4):284-288. 2. Lapointe L. Laboratory, Advance Healthcare Network. 2016;25(9):14.
3. Natera – data on file. 4. Reinert T, et al. JAMA Oncol. 2019. doi:10.1001/jamaoncol.2019.0528.

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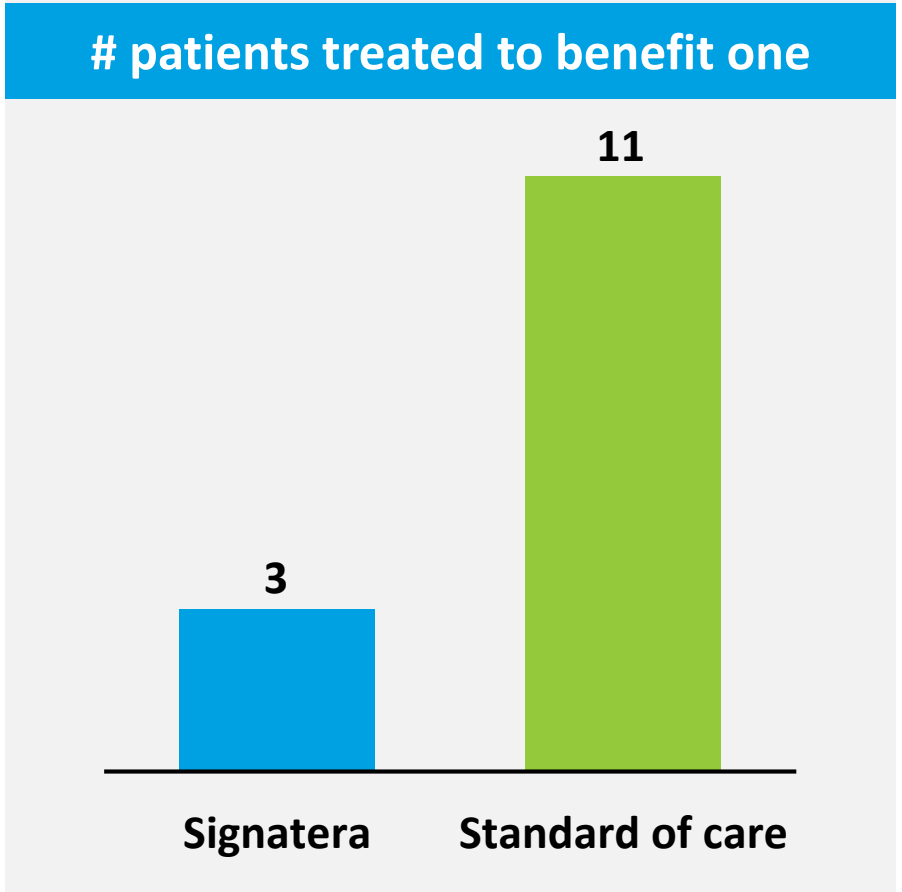
#2: Assessing risk/MRD status before adjuvant chemo

- Most patients are cured with surgery alone but still receive chemotherapy
- Adjuvant chemo is recommended for patients at high risk of relapse
  - High-risk patients often missed
  - Low-risk patients significantly overtreated
  - Serious treatment-related adverse events occur in 10-31% of patients[1]
- Using Signatera could reduce relapses, unnecessary treatment, and adverse events



1. Gray R, Barnwell J, McConkey C, et al. Adjuvant chemotherapy versus observation in patients with colorectal cancer: a randomized study. *Lancet*. Dec 15 2007;370(9604):2020-2029.

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Enabling a new market with Foundation Medicine

FOUNDATION MEDICINE®

Tumor sequencing leadership

+

natera®

Cell free DNA leadership

Personalized tumor monitoring for patients who have had FoundationOne®CDx

100,000+ patients annually receive FMI testing

50+ active biopharma partnerships

Expands access for cancer monitoring

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