

ONCOLOGY



A PROVIDER GUIDE TO

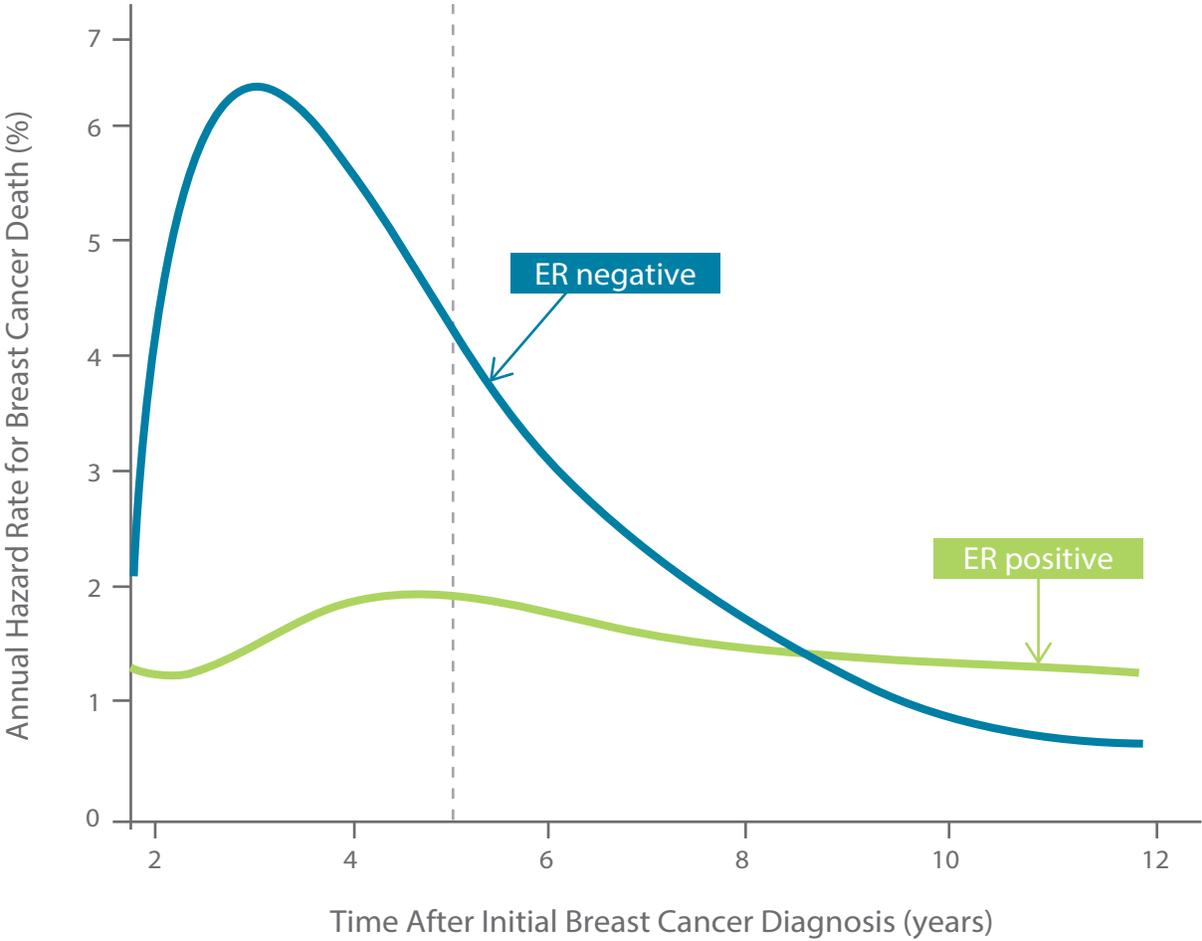


Prognostic Precision Providing Results  
You Can Trust

FOR ER+, HER2-, EARLY-STAGE BREAST CANCER

EndoPredict helps healthcare professionals guide ER+, HER2- early-stage breast cancer patients toward the appropriate treatment decision.

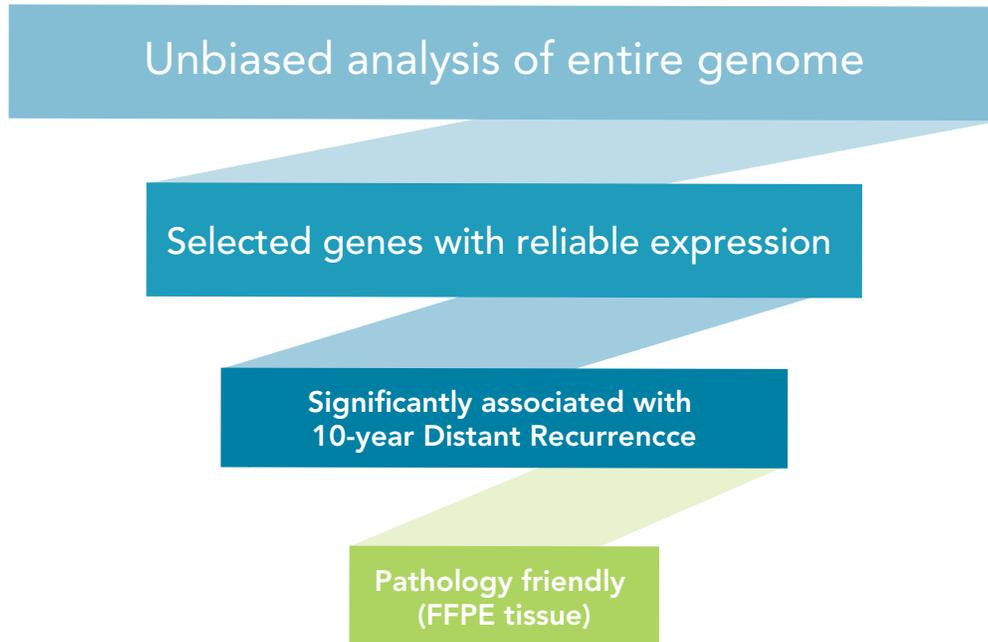
Long-term prognosis is particularly important in ER-positive breast cancer.<sup>1</sup>



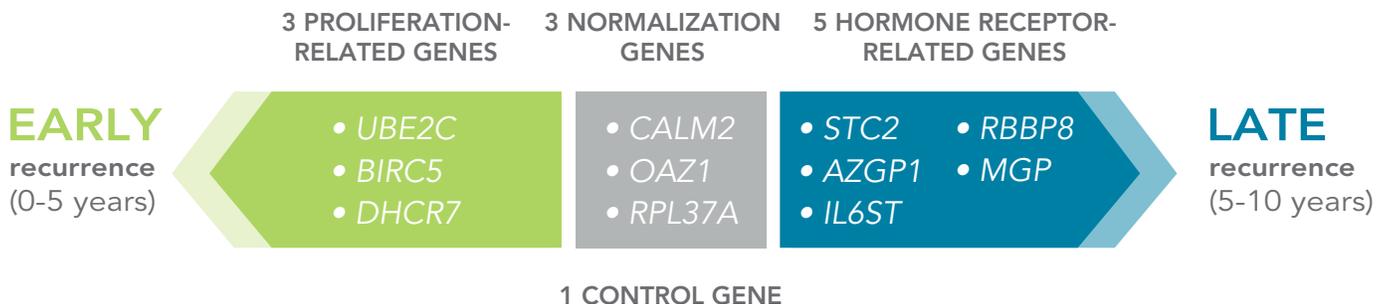
Of patients with ER+ breast cancer who experience recurrent disease, more than 50% occur after 5 years.<sup>1,2</sup>

EndoPredict was trained on a set of 964 ER+, HER2– breast tumors from women who were treated with adjuvant Tamoxifen only.

Gene selection process for 12-gene molecular score



## Correlation of Gene Expression with Early and Late Distant Recurrence<sup>4,5</sup>



## EPclin Risk Score Algorithm:



EndoPredict offers powerful prognostic information for both N0 and N1 patients.<sup>3,4,6,7</sup>

EndoPredict is a 2<sup>nd</sup> generation test validated in over 3,500 patients with ER+, HER2-, N0 and N1 disease and provides robust 10-year prognostic results.<sup>3,4,6,8</sup>

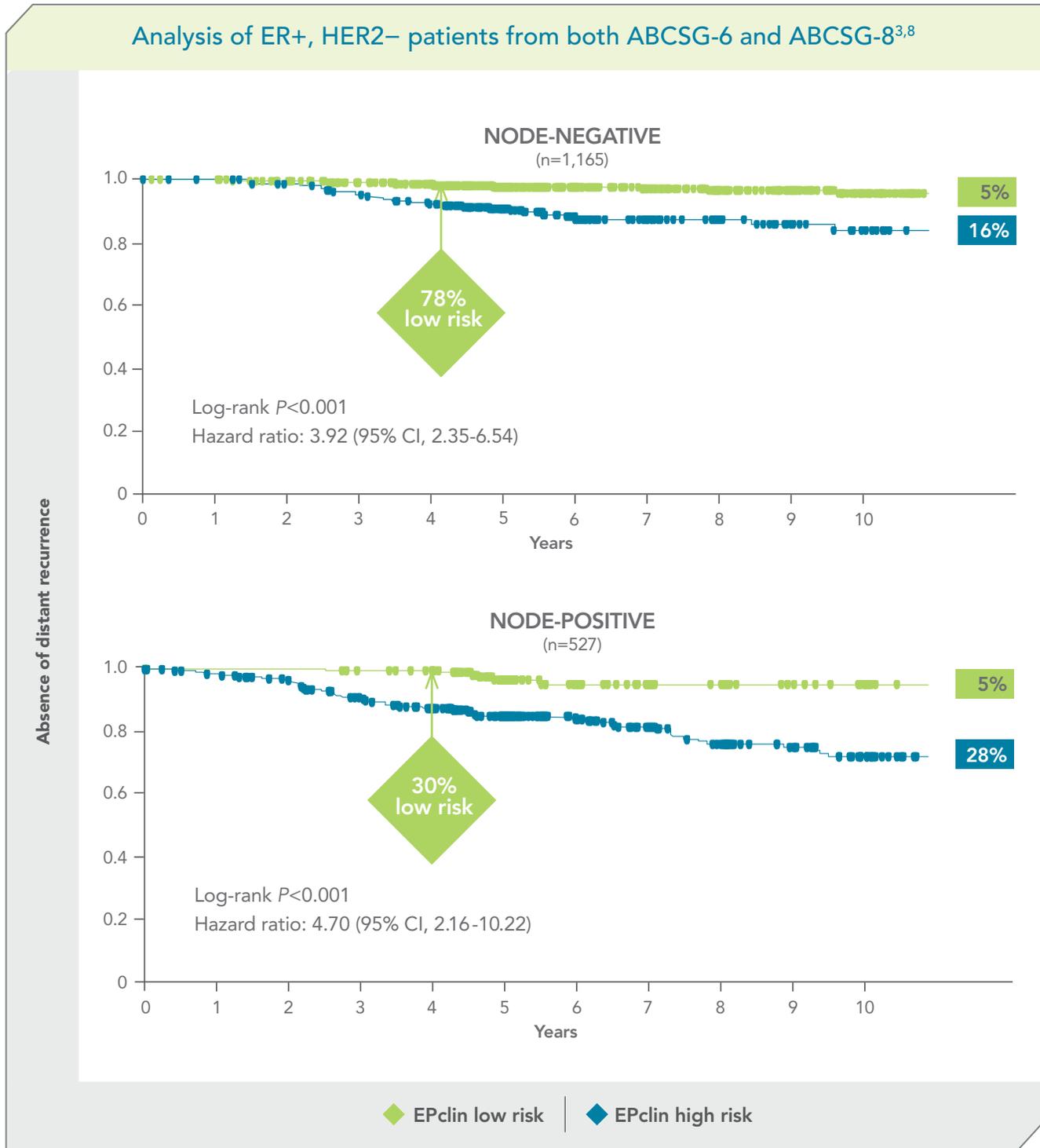
	Name of trial	N	Nodal status in cohort		Low-risk group average 10-year likelihood of distant recurrence
			N0	N+	
Training	Multicenter	964	65%	35%	7%
Validation I	ABCSG-6	378	60%	40%	4%
Validation II	ABCSG-8	1324	71%	29%	4%
Validation III	TransATAC	928	73%	27%	5.8%
Validation IV	GEICAM/9906	555	0%	100%	6.6%

Utilized in clinical practice in over 25,000 patients worldwide.

ACCORDING TO SIMON, HAYES AND PAIK:

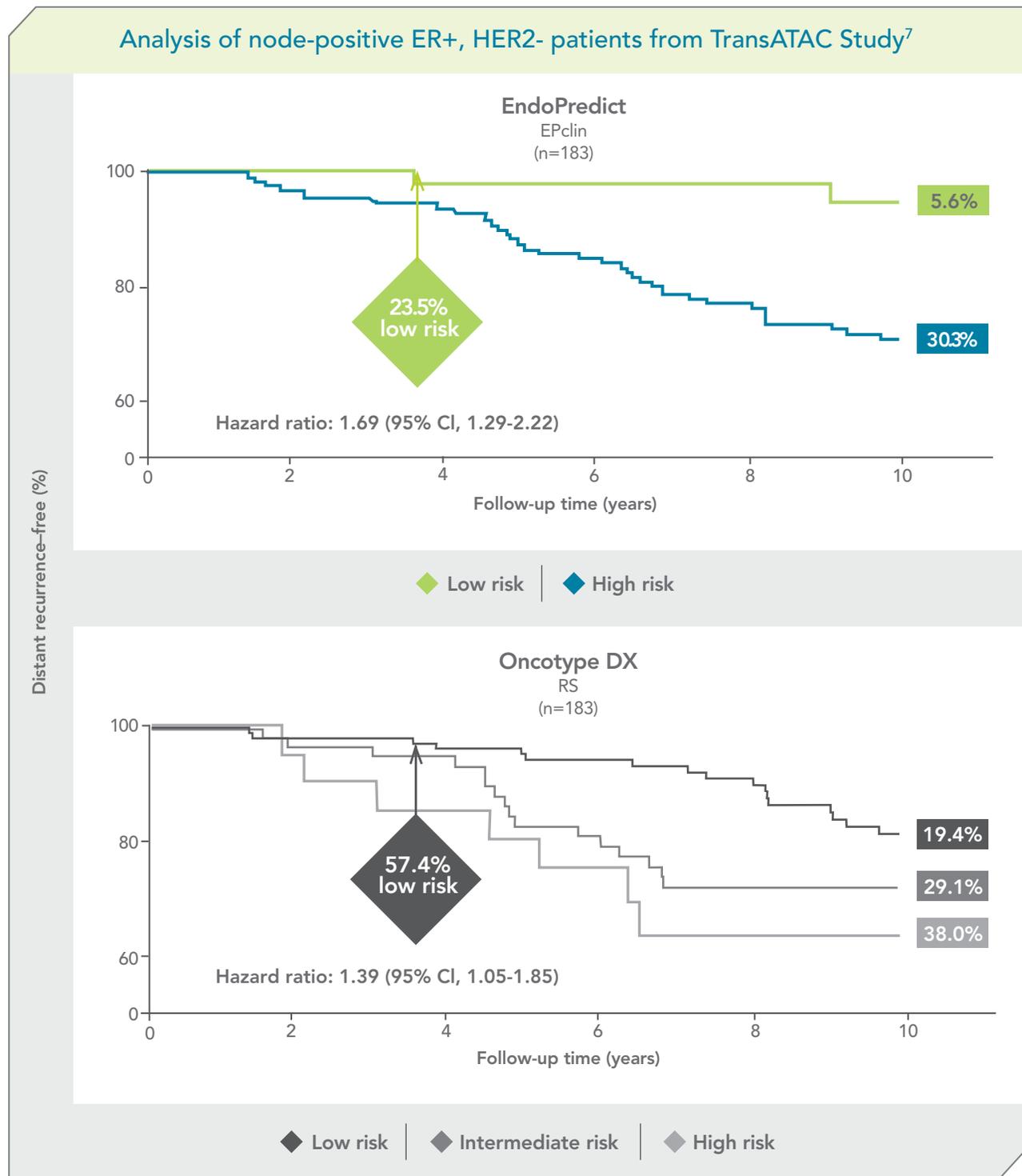
Studies using archived tissue from prospective studies **MEET LEVEL 1 EVIDENCE** when "the results are validated in at least one or more similarly designed studies using the same assay technique."<sup>14</sup>

EndoPredict is a second-generation assay trained and validated on 10-year distant recurrence data.



Filipits et al reported the independent validation of the EndoPredict molecular analysis and comprehensive EPclin score using data from two phase 3 studies, ABCSG-6 and ABCSG-8. Women in these studies received 5 years of endocrine therapy alone. Those in ABCSG-6 received either 5 years of tamoxifen or 2 years of tamoxifen and aminoglutethimide followed by 3 years of tamoxifen. Those in ABCSG-8 received either 5 years of tamoxifen or 2 years of tamoxifen followed by 3 years of anastrozole.<sup>3</sup>

EndoPredict demonstrates superior prognostic performance in node-positive disease.<sup>6,7</sup>

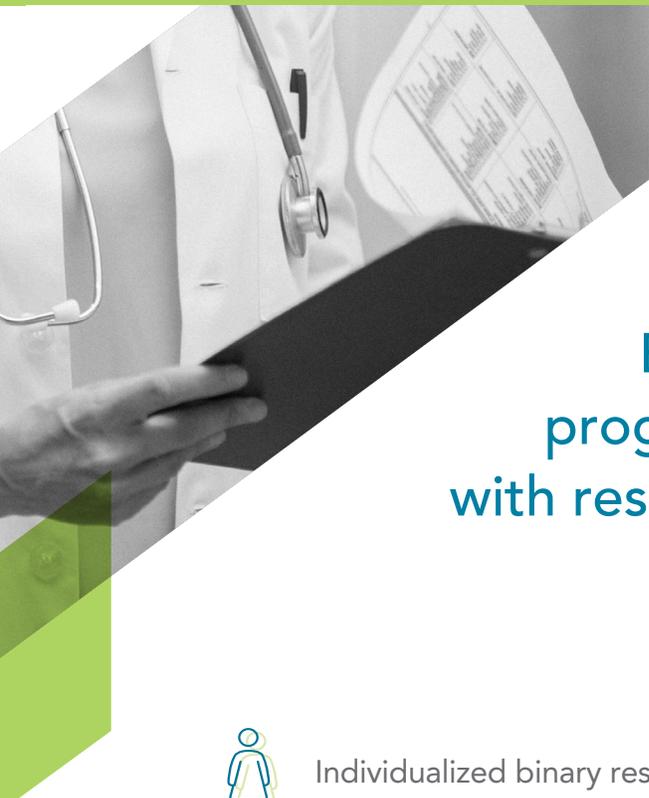


89.1% of node positive patients are classified as NON-HIGH risk by Oncotype DX.

Sestak et al: Kaplan-Meier analysis of distant recurrence in 183 node-positive postmenopausal women in TransATAC using the EndoPredict EPclin score and the Oncotype DX RS. Participants received only 5 years of endocrine therapy (either tamoxifen or anastrozole).<sup>7</sup>

**“Combined genomic and clinical models showed enhanced prognostic performance particularly for patients with 1 to 3 positive lymph nodes.”**

~ Sestak et al. JAMA Oncol 2018



## Why EndoPredict?

EndoPredict is proven to have prognostic power to provide you with results you can trust.



Individualized binary result with chemotherapy benefit



Lower cost vs other breast cancer recurrence tests



Fast 7-day turnaround



Inclusion of proliferation- and hormone receptor-related genes contributes to accurate assessment of early and late recurrence risk<sup>4,5</sup>



Better identifies a large percentage of low-risk patients (average of 6% recurrence)<sup>3,6,8</sup>



More than 70% of N0 patients<sup>7,8</sup>



Up to 30% of N+ patients<sup>7,8</sup>



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References: 1. Jatoi I, Anderson WF, Jeong J-H, Redmond CK. Breast cancer adjuvant therapy: time to consider its time-dependent effects. *J Clin Oncol.* 2011;29(17):2301-2304. 2. Sestak I, Dowsett M, Zabaglo L, et al. Factors predicting late recurrence for estrogen receptor-positive breast cancer. *J Natl Cancer Inst.* 2013;105(19):1504-1511. 3. Filipits M, Rudas M, Jakesz R, et al; for EP Investigators. A new molecular predictor of distant recurrence in ER-positive, HER2-negative breast cancer adds independent information to conventional clinical risk factors. *Clin Cancer Res.* 2011;17(18):6012-6020. 4. Filipits M, Rudas M, Jakesz R, et al; for EP Investigators. A new molecular predictor of distant recurrence in ER-positive, HER2-negative breast cancer adds independent information to conventional clinical risk factors [supplementary materials]. *Clin Cancer Res.* 2011;17(18):6012-6020. [http://clincancerres.aacrjournals.org/content/clinccanres/suppl/2011/08/01/1078-0432.CCR-11-0926.DC1/CCR-11-0926\\_Meth.T8.F9\\_rev.pdf](http://clincancerres.aacrjournals.org/content/clinccanres/suppl/2011/08/01/1078-0432.CCR-11-0926.DC1/CCR-11-0926_Meth.T8.F9_rev.pdf). Accessed February 9, 2017. 5. Dubsky P, Brase JC, Jakesz R, et al; on behalf of Austrian Breast and Colorectal Cancer Study Group. The EndoPredict score provides prognostic information on late distant metastases in ER+/HER2- breast cancer patients. *Br J Cancer.* 2013;109(12):2959-2964. 6. Buus R, Sestak I, Kronenwett R, et al. Comparison of EndoPredict and EPclin with Oncotype DX recurrence score for prediction of risk of distant recurrence after endocrine therapy. *J Natl Cancer Inst.* 2016;108(11):djw149. doi:10.1093/jnci/djw149. 7. Sestak I, Buus R, Cuzick J, et al; Comparison of the Performance of 6 Prognostic Signatures for Estrogen Receptor-Positive Breast Cancer A Secondary Analysis of a Randomized Clinical Trial. *JAMA Oncol.* Published online Feb 15, 2018 doi:10.1001/jamaoncol.2017.5524 8. Data on file. Myriad Genetics Inc. 9. Martin M, Brase JC, Calvo L, et al. Clinical validation of the EndoPredict test in node-positive, chemotherapy-treated ER+/HER2- breast cancer patients: results from the GEICAM 9906 trial. *Breast Cancer Res.* 2014;16(2):R38. doi:10.1186/bcr3642. 10. Harris LN, Ismaila N, McShane LM, et al. Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology clinical practice guideline. *J Clin Oncol.* 2016;34(10):1134-1150. 11. Senkus E, Kyriakides S, Ohno S, et al; ESMO Guidelines Committee. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol.* 2015;26(Suppl 5):v8-v30. 12. Gnant M, Thomssen C, Harbeck N. St. Gallen/Vienna 2015: A Brief Summary of the Consensus Discussion. *Breast Care (Basel).* 2015;10(2):124-130. 13. Leitke C, Thill M; AGO Breast Committee. AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2016. *Breast Care (Basel).* 2016;11(3):204-214. 14. Curigliano G, Burstein H, Winer E, et al. De-escalating and escalating treatments for early-stage breast cancer: the St. Gallen International Expert Consensus Conference on the Primary Therapy of Early Breast Cancer. *Ann Oncol* 2017;28:1700-1712.

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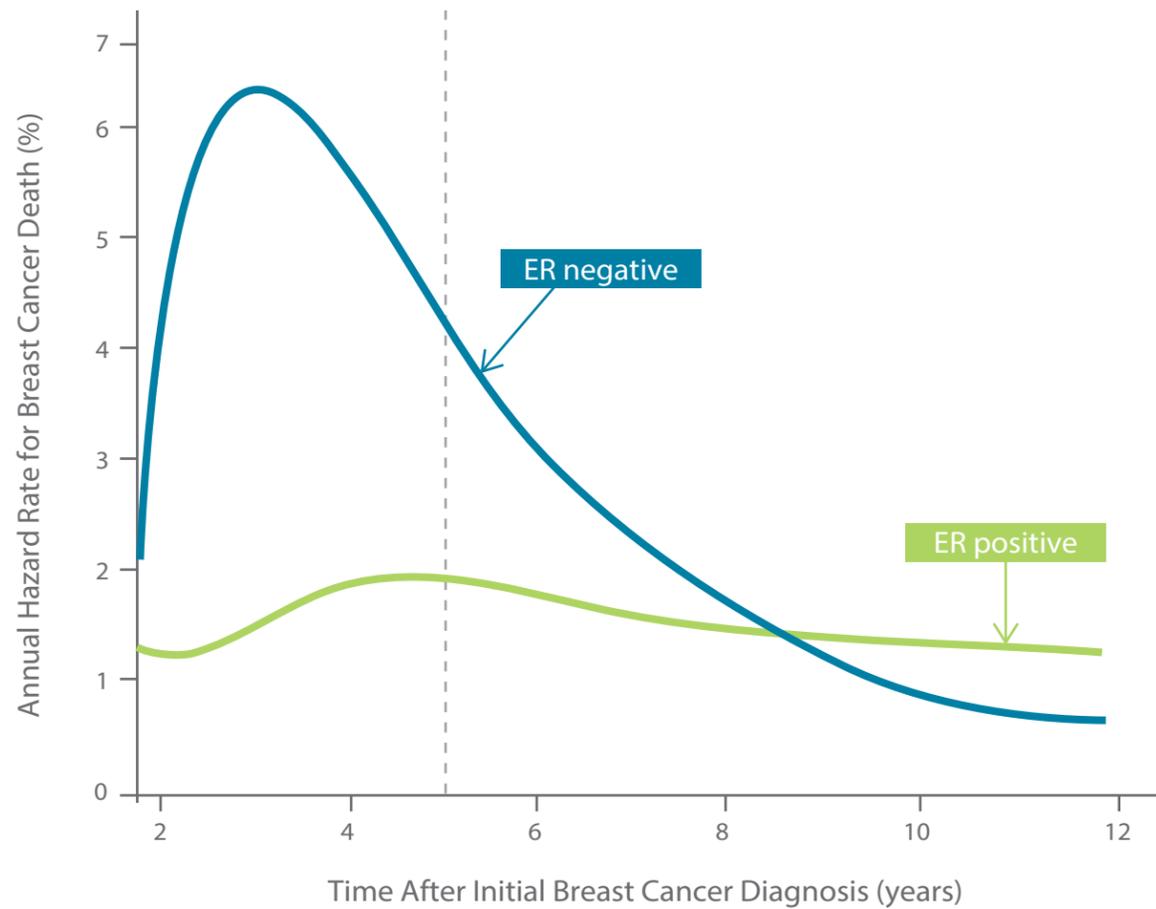
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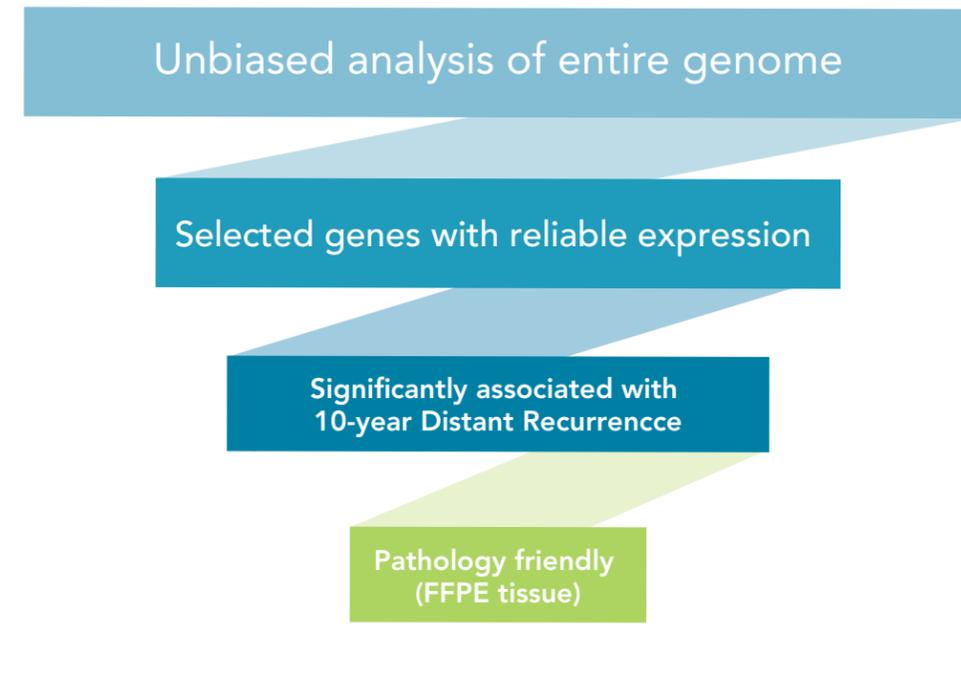
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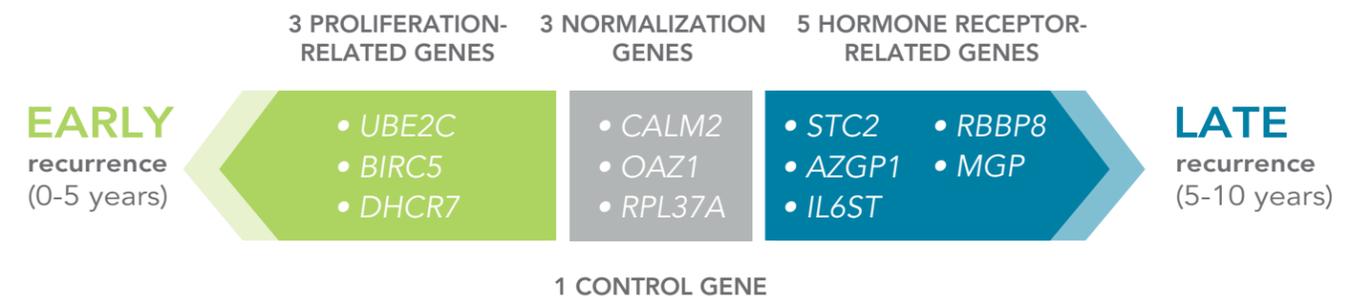
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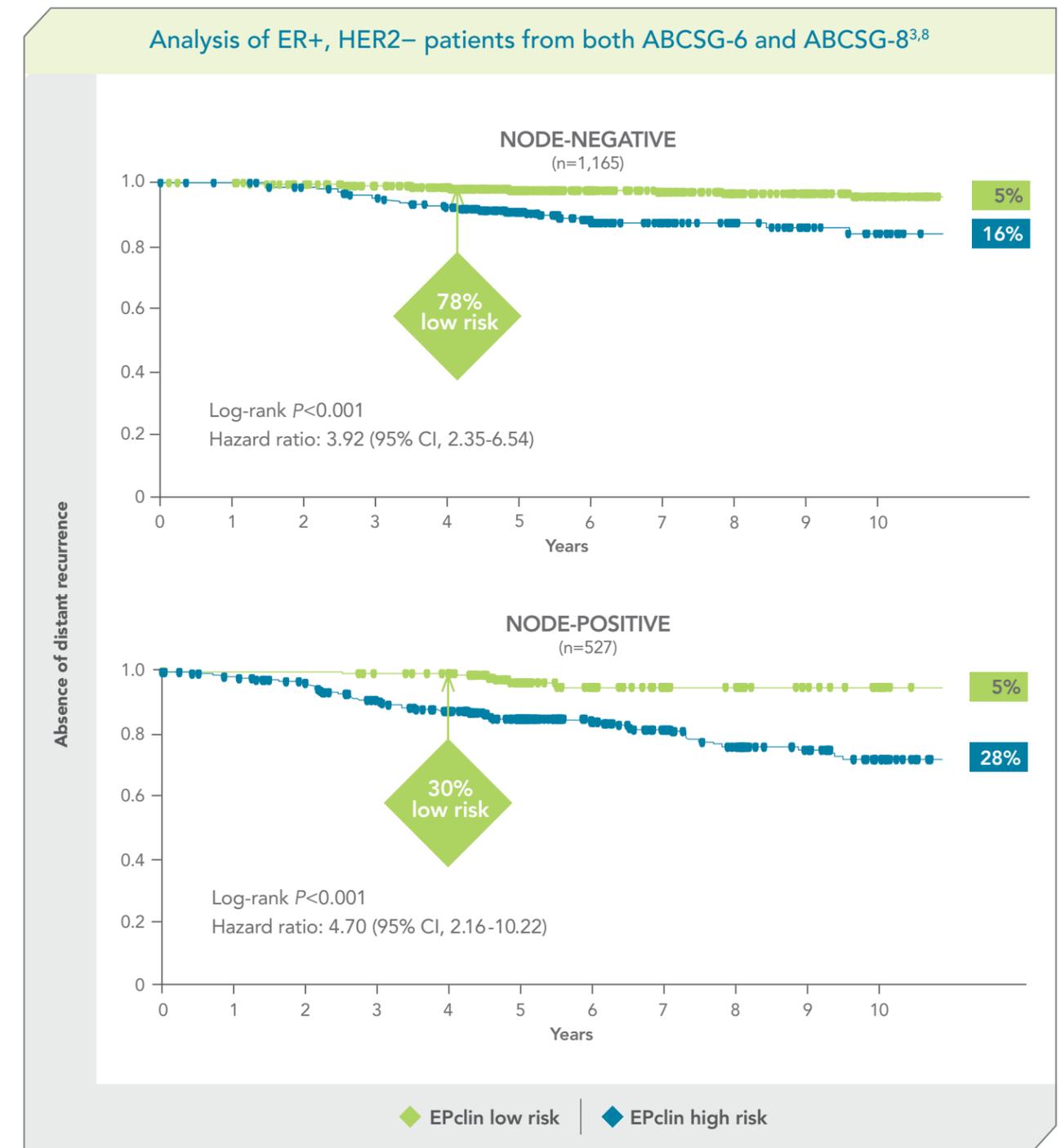
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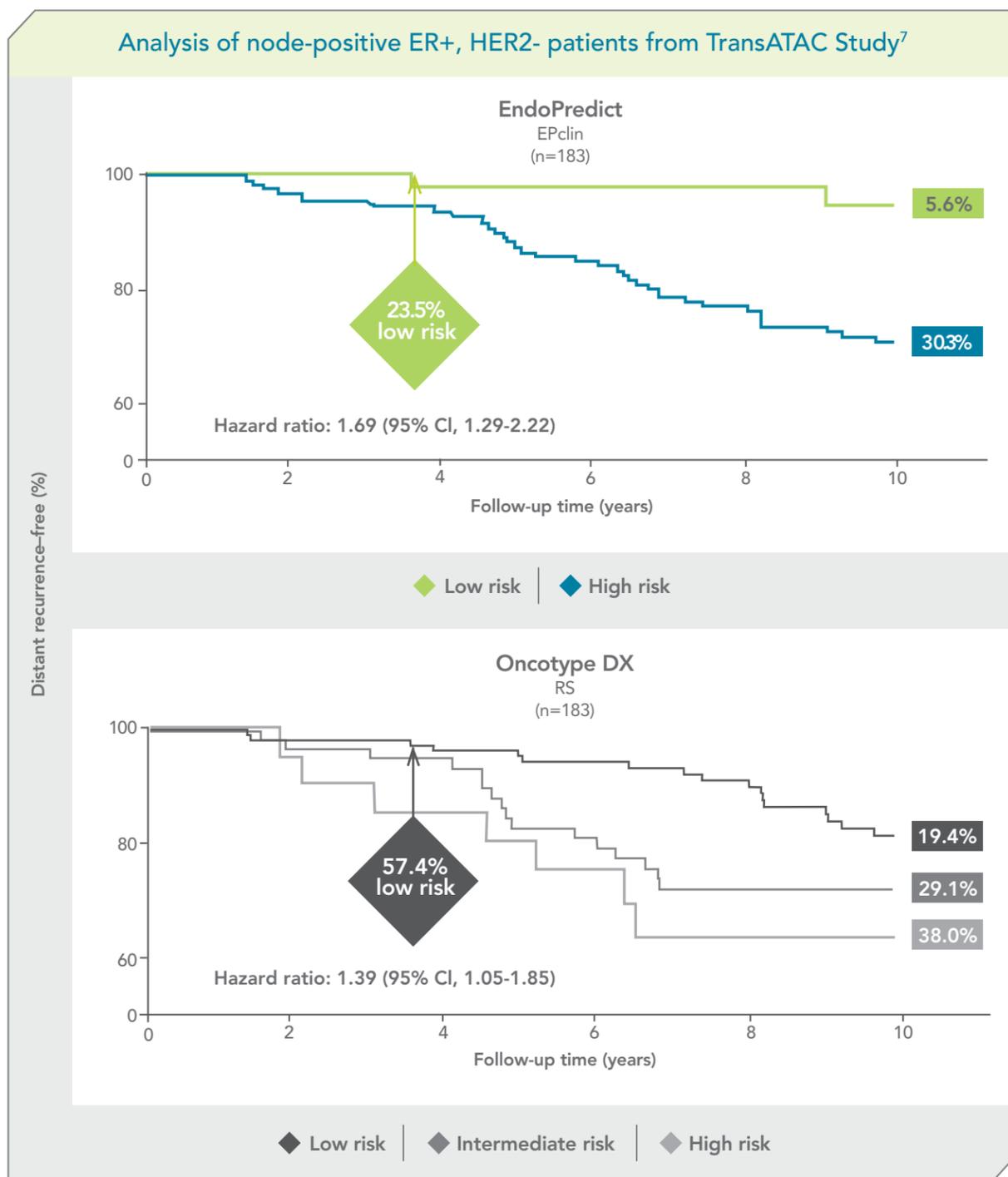
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