

WHEN DETERMINING 2ND LINE + TREATMENT OPTIONS FOR NSCLC PATIENTS, VERISTRAT HELPS PHYSICIANS GUIDE THERAPY

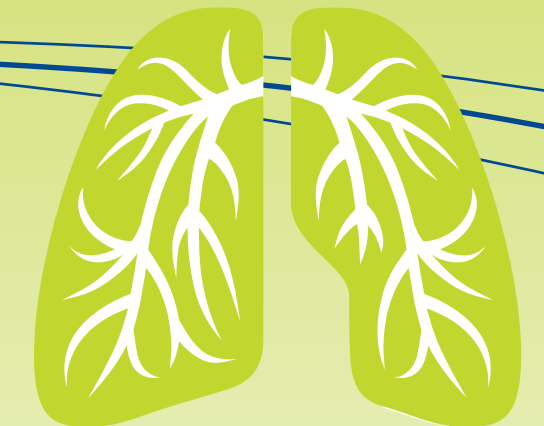
- VeriStrat is a pretreatment serum test that predicts response to erlotinib in patients with NSCLC
- VeriStrat identifies candidates for EGFR therapy independent of patient characteristics, such as smoking history and histology, and genetic mutational status (EGFR and KRAS)
- VeriStrat requires a simple blood draw
- Results are returned in less than 72 hours

To order call:  **VeriStrat®
Support Hotline**
1-866-432-5930

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For more information on VeriStrat, visit www.VeriStratSupport.com.



VERISTRAT PREDICTS RESPONSE TO ERLOTINIB IN NON-SMALL CELL LUNG CANCER PATIENTS¹



MULTIPLE TREATMENT OPTIONS ARE AVAILABLE FOR PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

According to NCCN Guidelines, treatment options for 2nd line + NSCLC include²:

- Docetaxel
- Pemetrexed
- Erlotinib
- Platinum-based combinations, if erlotinib given 1st line

Based on randomized Phase III trials, current therapies demonstrated a median overall survival between 6-8 months in 2nd and 3rd line NSCLC patients.

Phase III Trial	Regimen	Sample Size	OS(mos)
TAX320*	Docetaxel	125	5.7
	Vinorelbine or Ifosfamide	122	5.6
Alimta Registration Trial [†]	Pemetrexed	283	8.3
	Docetaxel	288	7.9
INTEREST [‡]	Gefitinib	733	7.6
	Docetaxel	733	8.0
BR.21 Trial [§]	Erlotinib	488	6.7
	Placebo	243	4.7

*Fossella et al., JCO 2000
[†]Hanna et al., JCO 2004
[‡]Kim et al., Lancet 2008
[§]Shepherd et al., NEJM 2005

MEDIAN SURVIVAL OF 6-8 MONTHS FOR 2ND & 3RD LINE NSCLC PATIENTS HAS BEEN REPORTED

IDENTIFYING APPROPRIATE THERAPY FOR PATIENTS IS KEY TO IMPROVING TREATMENT OUTCOMES

Therapeutic decisions are commonly based on patient characteristics including³:

- Performance status
- Histology
- Ethnicity
- Smoking history

However, recent developments in biomarkers are identifying patient groups that perform better on targeted therapies.⁴

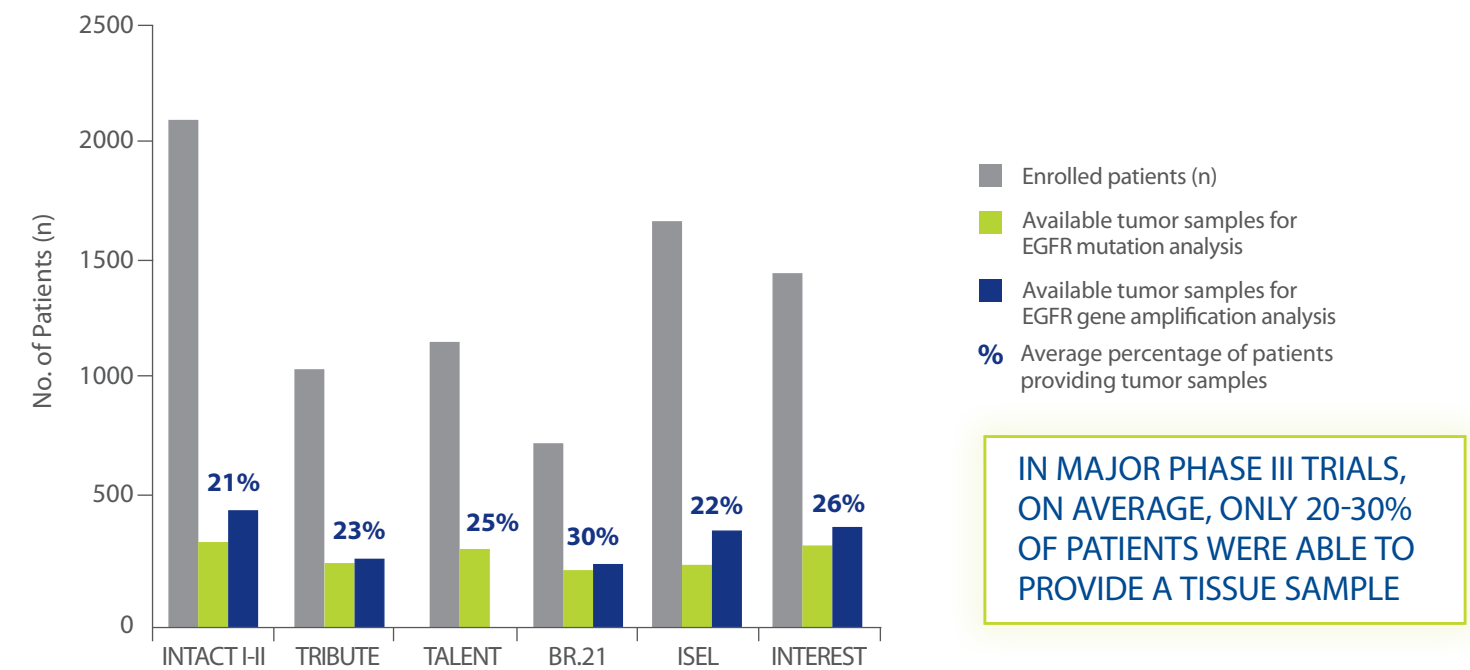
IDENTIFYING APPROPRIATE PATIENTS FOR 2ND LINE + THERAPY IS CRITICAL TO IMPROVING PATIENT OUTCOMES.

PRACTICAL CONSIDERATIONS FOR BIOMARKER TESTING IN NSCLC

Obtaining tissue for biomarker testing in the 2nd line + setting, poses a significant challenge

- Collection of biopsy samples from patients is invasive⁵
- Patients with comorbidities and poor performance status may not be able to provide tissue samples⁵
- NSCLC tumors are heterogeneous and EGFR expression can be different between the primary tumor and metastases^{6,7}

LOW AVAILABILITY OF TISSUE BIOPSY MATERIAL FROM KEY EGFR TRIALS IN NSCLC⁸



IN MAJOR PHASE III TRIALS, ON AVERAGE, ONLY 20-30% OF PATIENTS WERE ABLE TO PROVIDE A TISSUE SAMPLE

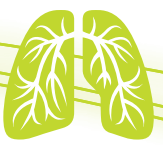
A minority of NSCLC patients harbor EGFR and KRAS mutations

Mutational Status	% of North American Patients
EGFR Mutation +	15-20% ⁹
FISH +	~15% ⁹
KRAS Mutation +	15-20% ¹⁰

Lengthy Analysis Time

- Analysis of tissue biopsy samples can take several weeks

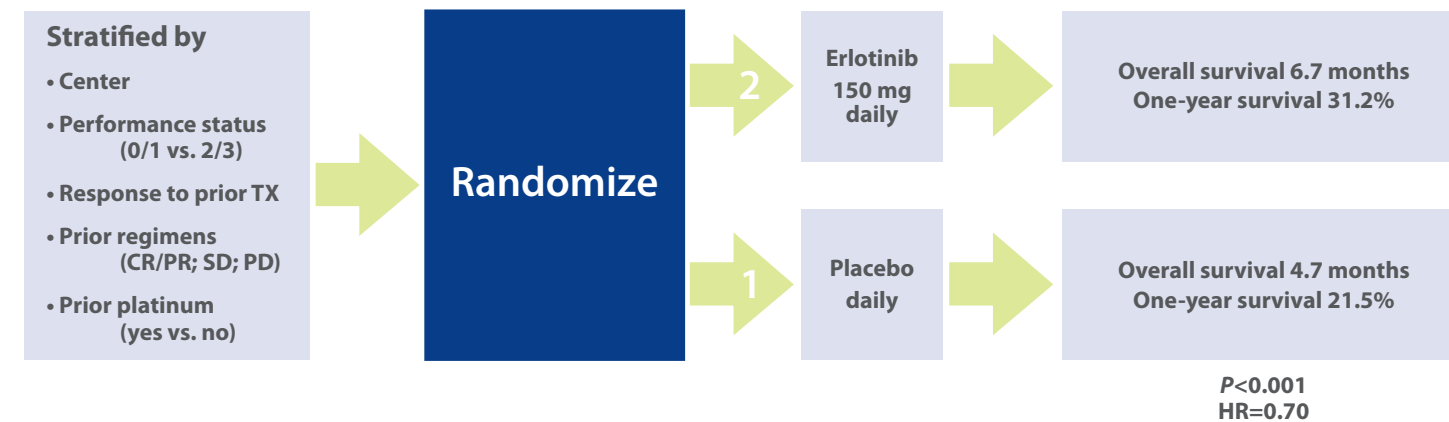
A PRACTICAL, NONINVASIVE SOLUTION IS NEEDED TO IDENTIFY PATIENTS LIKELY TO BENEFIT FROM TARGETED THERAPY.



BR.21: ERLOTINIB IN PREVIOUSLY TREATED NSCLC⁴

BR.21 has been extensively analyzed to determine if biomarkers can predict patient outcomes to erlotinib therapy

BR.21 SCHEMA (n=731)

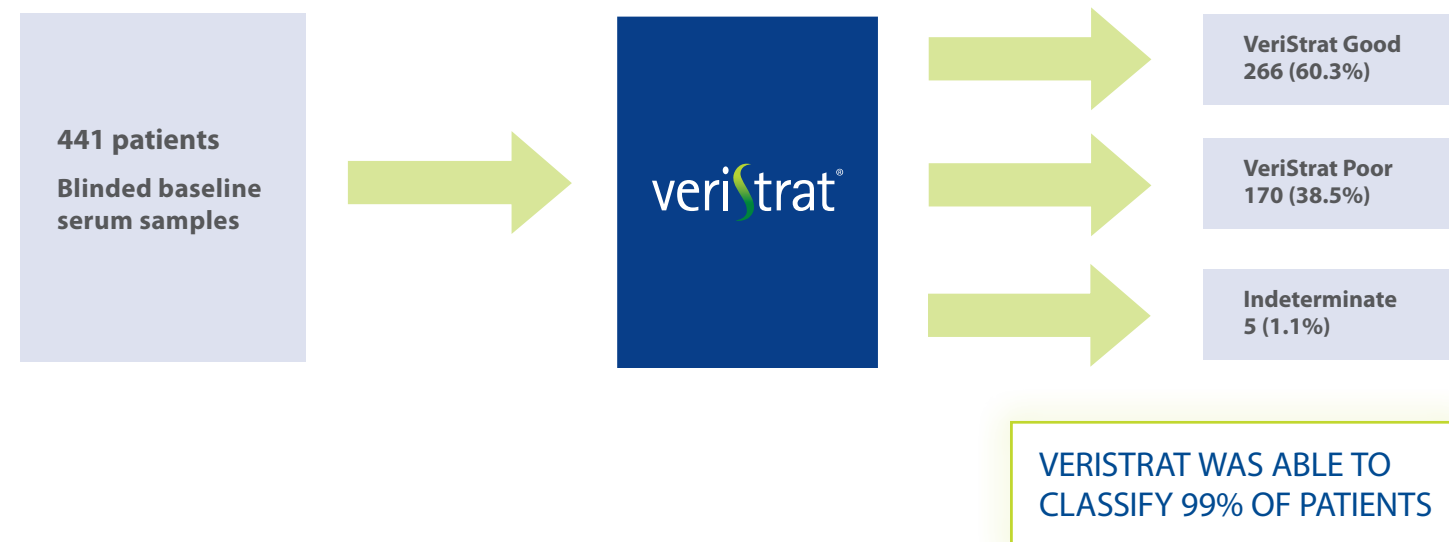


BR.21: VERISTRAT ANALYSIS

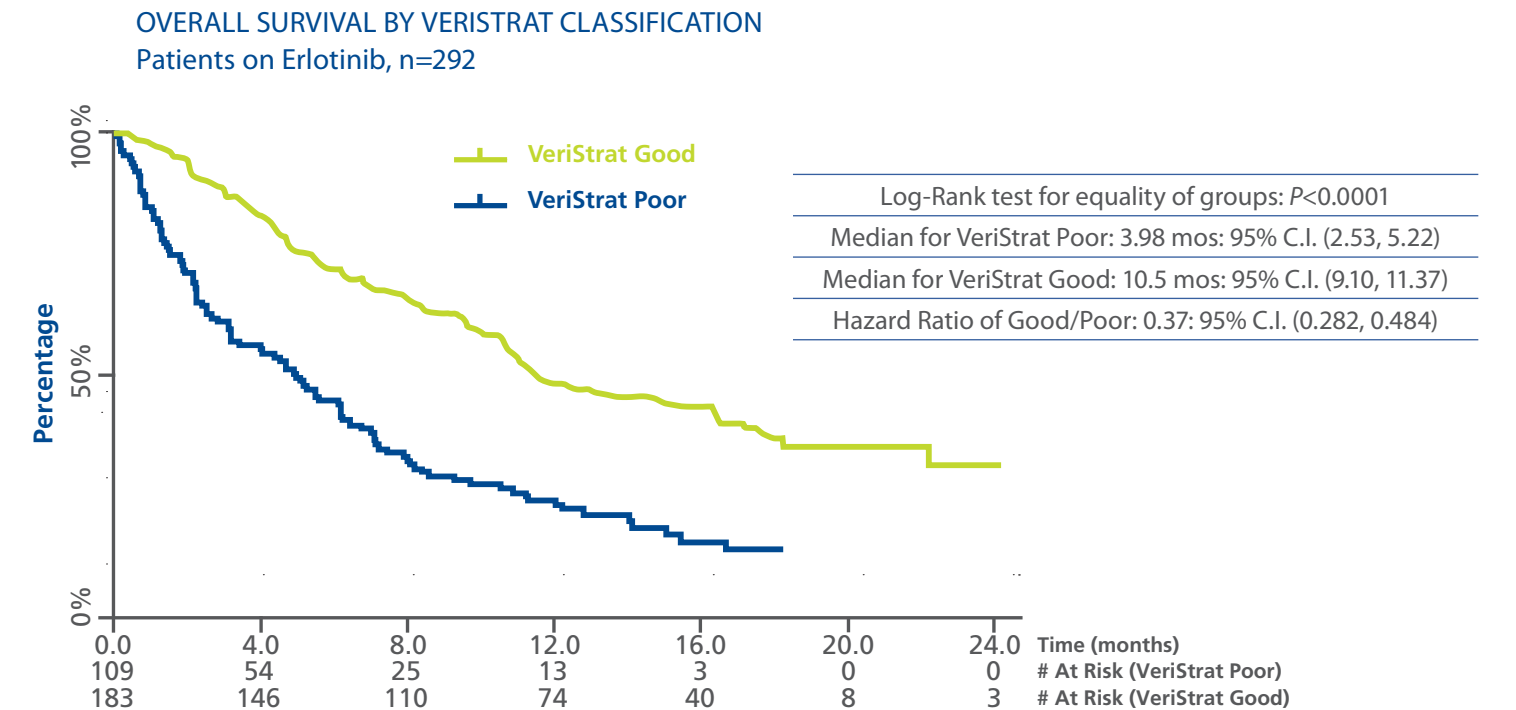
VeriStrat was applied retrospectively to a subset of the patient population from BR.21

- The retrospective VeriStrat analysis involved 441 of 731 patients from the BR.21 Trial and classified patients as VeriStrat Good or VeriStrat Poor based on a specific proteomic profile.¹
 - The VeriStrat Poor proteomic profile is thought to be associated with a host-tumor response, possibly leading to the downstream activation of the MAPK pathway independently of the EGF receptor, and thus to resistance to EGFR-TKIs.

BR.21 TRIAL SCHEMA WITH VERISTRAT (n=441)



VERISTRAT GOOD PATIENTS TREATED WITH ERLOTINIB HAD A SIGNIFICANTLY BETTER OVERALL SURVIVAL THAN VERISTRAT POOR PATIENTS TREATED WITH ERLOTINIB¹



VERISTRAT PROVIDES A CLEAR TEST RESULT, VERISTRAT GOOD OR VERISTRAT POOR, THAT CORRELATES WITH SURVIVAL OUTCOMES AFTER EGFR-THERAPY.

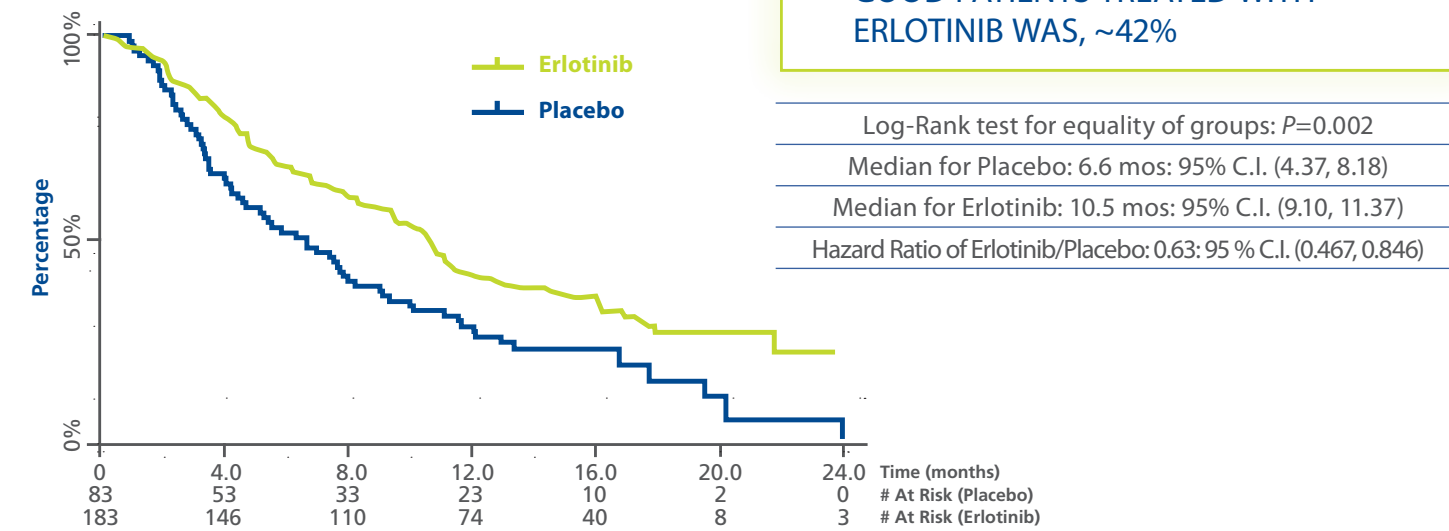


WHEN TREATED WITH ERLOTINIB, VERISTRAT GOOD PATIENTS HAD A MEDIAN OVERALL SURVIVAL OF 10.5 MONTHS¹

VeriStrat Good patients had a statistically significant improvement in overall survival when treated with erlotinib as compared to placebo

OVERALL SURVIVAL

Patients Classified as VeriStrat Good, n=266

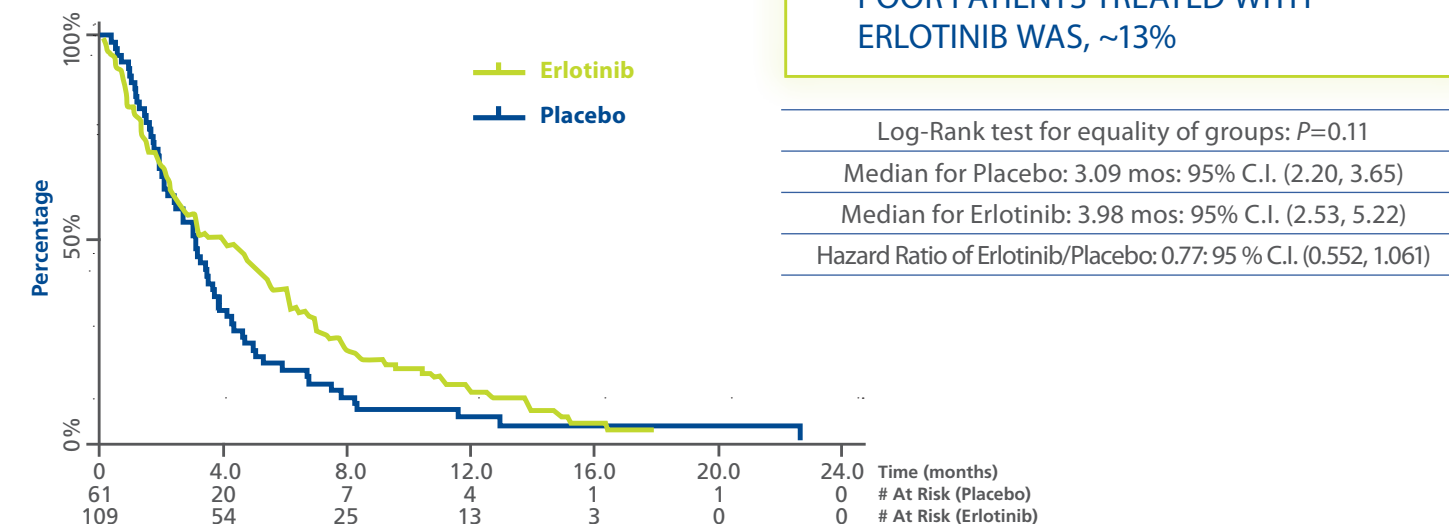


WHEN TREATED WITH ERLOTINIB VERISTRAT POOR PATIENTS DID NOT HAVE A STATISTICALLY SIGNIFICANT SURVIVAL ADVANTAGE¹

VeriStrat Poor patients had no statistically significant improvement in overall survival when treated with erlotinib as compared to placebo

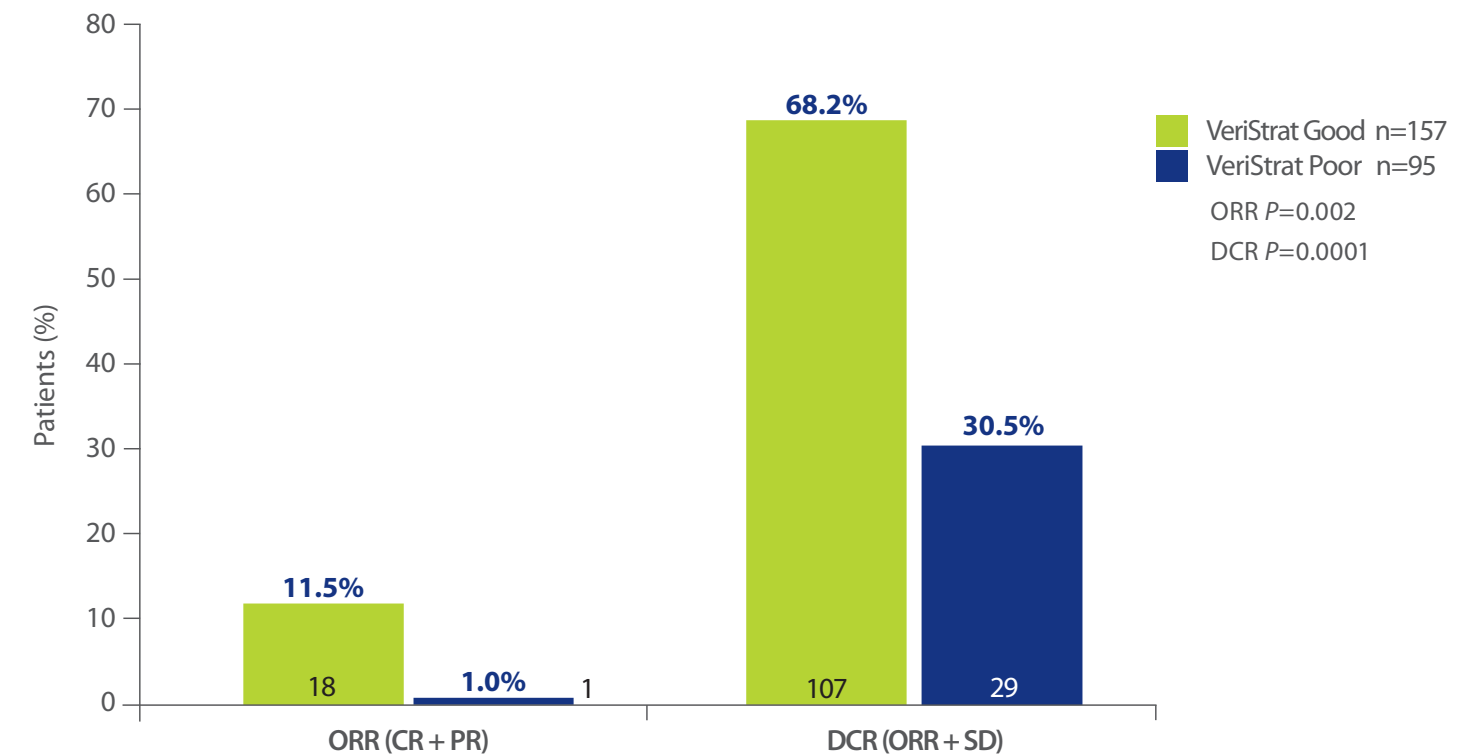
OVERALL SURVIVAL

Patients Classified as VeriStrat Poor, n=170



VERISTRAT IS PREDICTIVE OF RESPONSE RATE AND DISEASE CONTROL RATE¹

EVALUABLE PATIENTS TREATED WITH ERLOTINIB, n=252



68% OF VERISTRAT GOOD PATIENTS EXPERIENCED DISEASE CONTROL

VERISTRAT STATUS IS INDEPENDENT OF TISSUE MARKERS IN BR.21¹

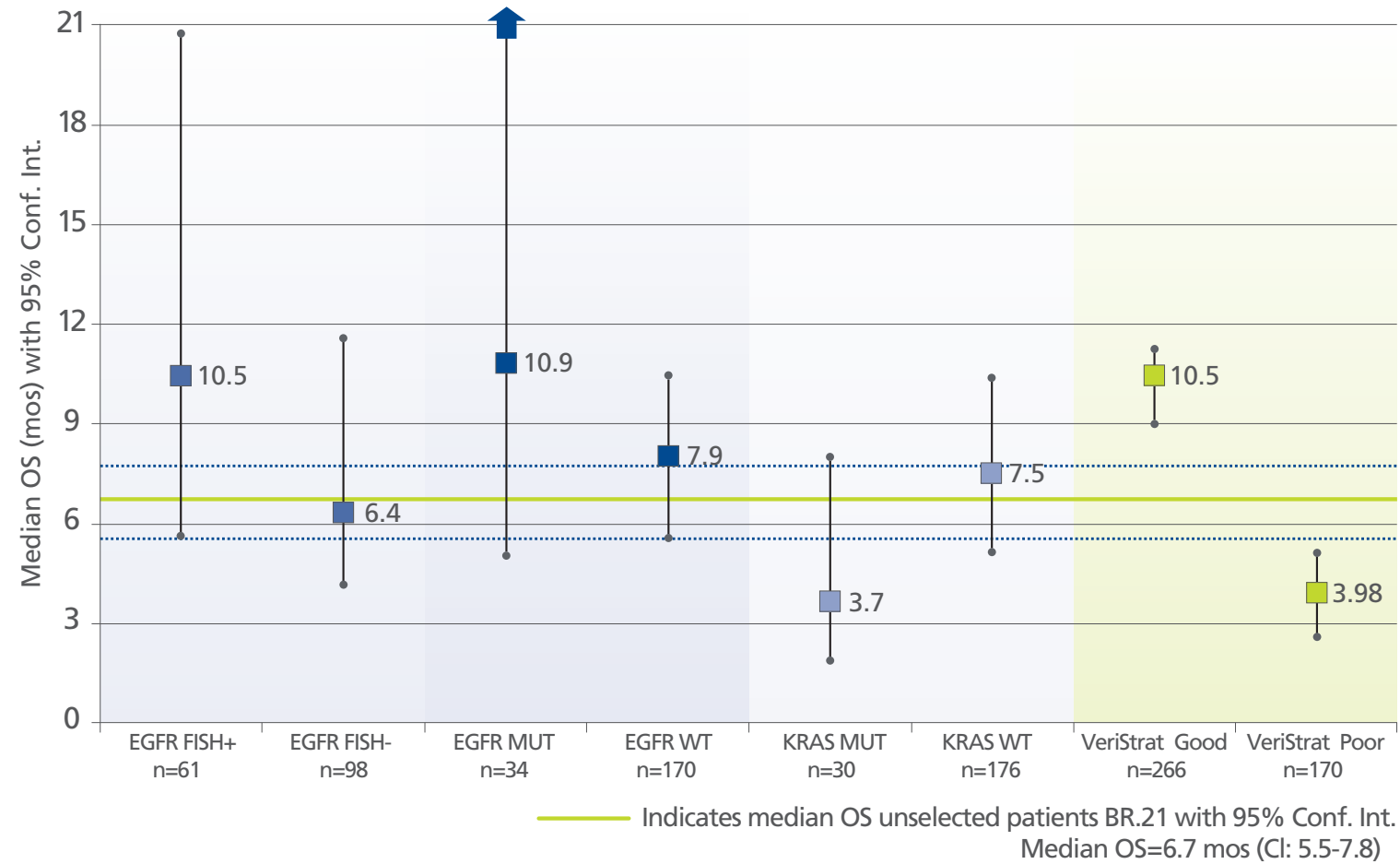
BR.21 - VERISTRAT STATUS BY FISH COPY NUMBER, EGFR AND KRAS MUTATION STATUS

		VeriStrat Good (n=266)	VeriStrat Poor (n=170)	P value
EGFR Mutation n=14 n=116 n=306	Mutated	10 (71%)	4 (29%)	0.62
	Wild Type	68 (59%)	48 (41%)	
	Unknown	188 (61%)	118 (39%)	
EGFR FISH n=43 n=56 n=337	FISH +	24 (56%)	19 (44%)	0.76
	FISH -	34 (61%)	22 (39%)	
	Unknown	208 (62%)	129 (38%)	
KRAS Mutation n=20 n=111 n=305	Mutated	13 (65%)	7 (35%)	0.93
	Wild Type	67 (60%)	44 (40%)	
	Unknown	186 (61%)	119 (39%)	



VERISTRAT PROVIDES CLEAR VALUE IN SELECTING PATIENTS LIKELY OR NOT LIKELY TO BENEFIT FROM ERLOTINIB

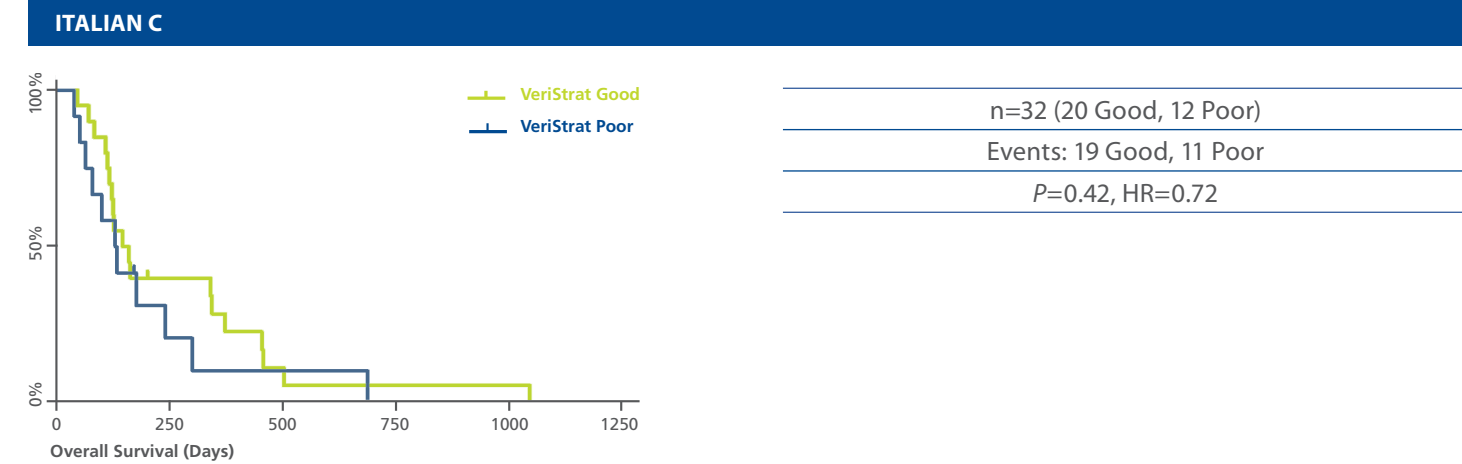
BR.21 - MEDIAN OS ERLOTINIB ARM BY BIOMARKER



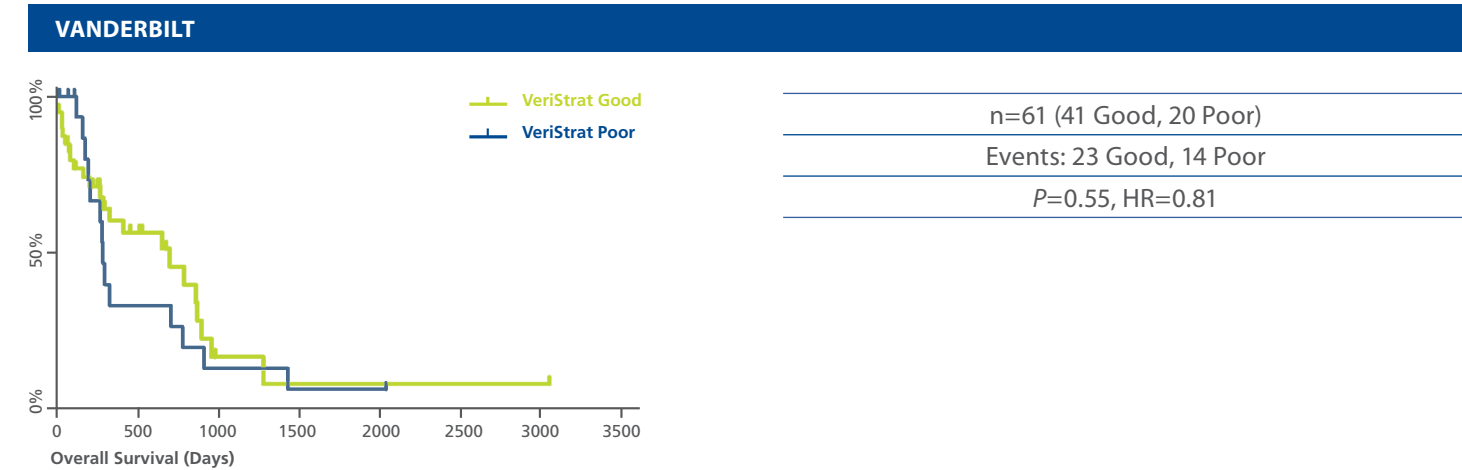
VERISTRAT IS THE ONLY NONINVASIVE TEST THAT PROVIDES CLEAR GUIDANCE FOR MAKING A TREATMENT DECISION IN THE 2ND LINE + SETTING.

IN PREVIOUS SEPARATE STUDIES, VERISTRAT HAS NOT SHOWN SIGNIFICANT SEPARATION IN CHEMOTHERAPY-TREATED OR POSTSURGERY NSCLC PATIENTS¹¹

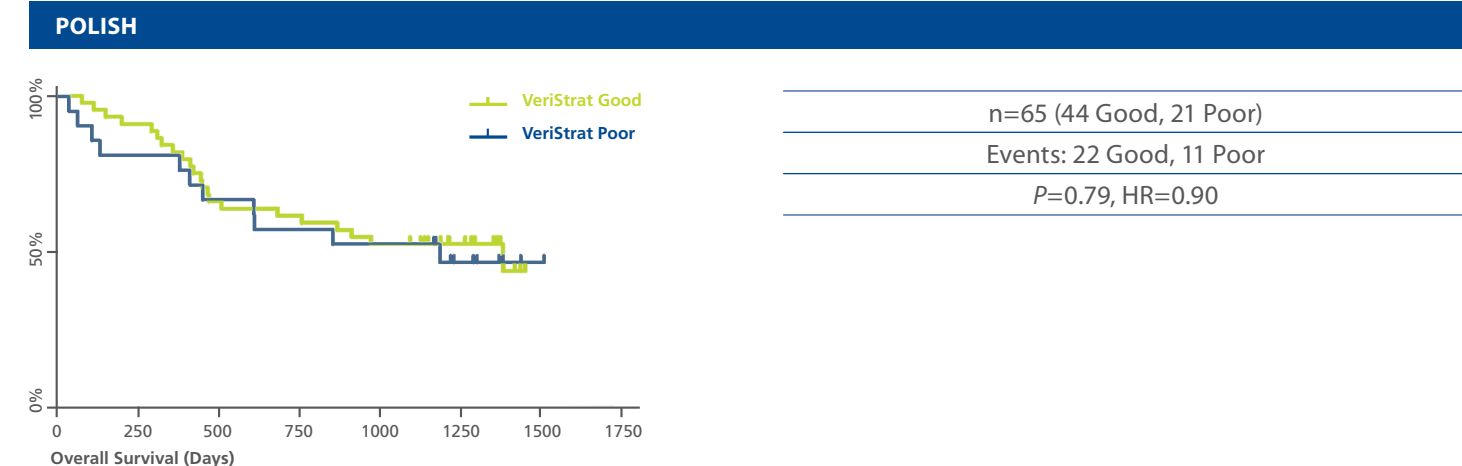
CONTROL RESULTS: ADVANCED NSCLC PATIENTS WITH UNRESECTABLE DISEASE TREATED WITH CHEMOTHERAPY*



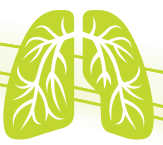
CONTROL RESULTS: ADVANCED NSCLC PATIENTS WITH UNRESECTABLE DISEASE TREATED WITH CHEMOTHERAPY*



CONTROL RESULTS: EARLY STAGE NSCLC PATIENTS THAT RECEIVED SURGERY ALONE AND NO EGFR TKIS*

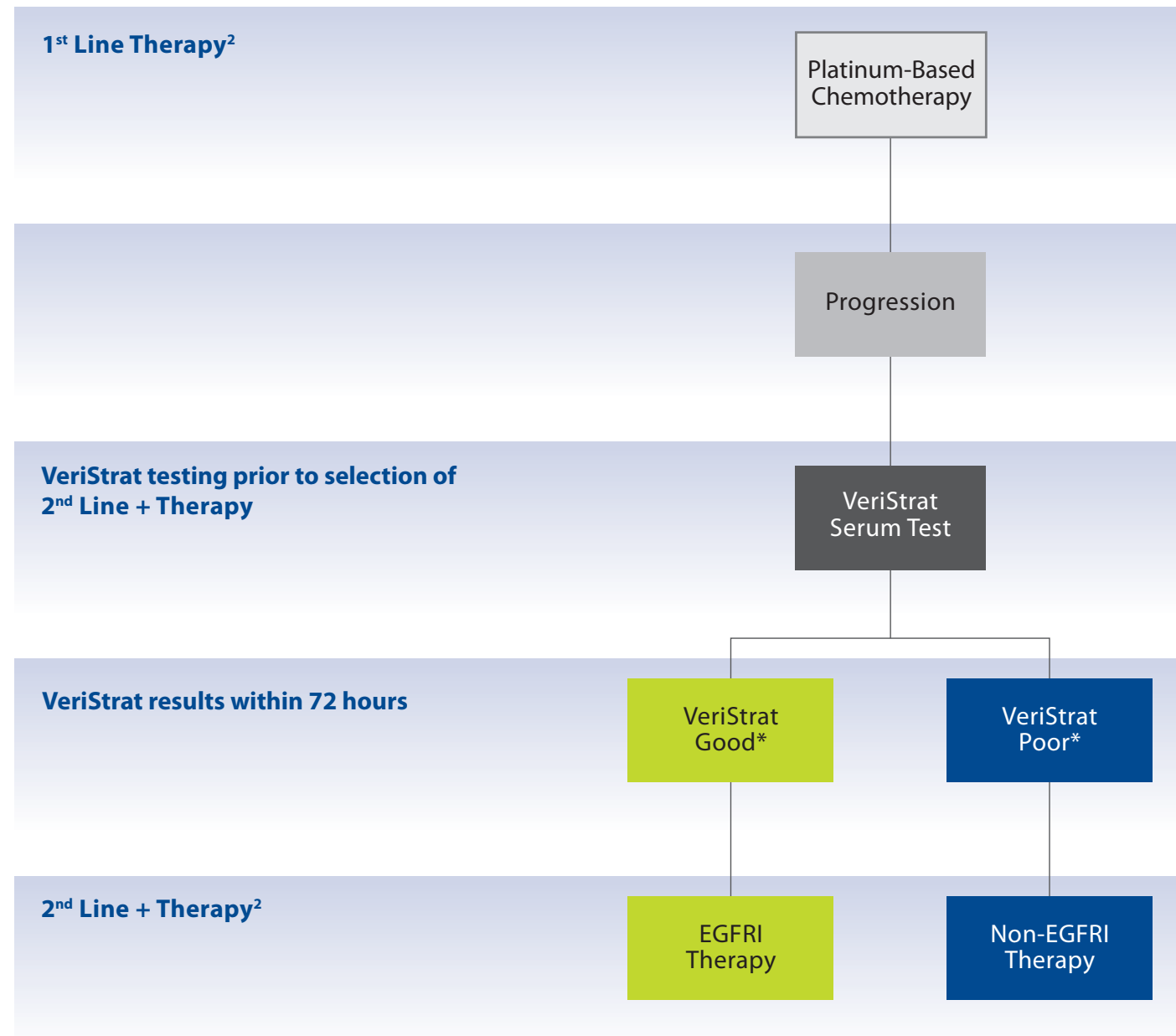


*Data and figures have been updated since publication in Taguchi et al.¹¹



INCORPORATING THE VERISTRAT SERUM TEST INTO ADVANCED NSCLC PATIENT MANAGEMENT

VeriStrat in clinical practice



²VeriStrat test results should be used in combination with the patient's clinical history, other diagnostic tests, and clinicopathological factors, customarily evaluated by a qualified physician.

DISCOVER HOW VERISTRAT CAN HELP YOU GUIDE THERAPY

1. Call the Support Hotline

- Simply call the VeriStrat Support Hotline and inform the customer service representative that you would like to begin VeriStrat testing

2. Order test kits

- The customer service representative will assist you in accommodating your facility's needs, including shipment of test kits and training

3. Start testing

- Follow instructions for collecting and shipping serum to the Biodesix CLIA-accredited lab
- Results will be sent to you within 72 hours of sample shipment

To order call:  **VeriStrat[®]**
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