

Studienname	ADAPTlate A randomized, controlled, open-label, phase-III trial on Adjuvant Dynamic marker - Adjusted Personalized Therapy comparing abemaciclib combined with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy in (clinical or genomic) high risk, HR+/HER2- early breast cancer															
Sponsor/ Studiencode	WSG WSG-AM11															
Setting	HR pos. HER2 neg. eBC, adjuvante Therapie															
Primäres Studienziel	Invasives DFS															
Studiendesign	<p>Completed or ongoing adjuvant endocrine therapy (ET) AND ET started at least 12 month before patient enrollment AND Primary diagnosis was 6 years or less before enrollment</p> <table border="1"> <thead> <tr> <th></th> <th>After neoadjuvant chemotherapy</th> <th>After adjuvant treatment (chemotherapy and/or ET)</th> </tr> </thead> <tbody> <tr> <td>Known high clinical risk</td> <td> <ul style="list-style-type: none"> • (cN 2-3 with pCR or non-pCR) or ypN 2-3 or • (cN 1 or G3 tumor and non-pCR) or ypN1 </td> <td> <ul style="list-style-type: none"> • pN 0-1 and G3 with Ki-67 pre-treatment > 40% or • pN 0-1 and high CTS5 score or • pN 2-3 </td> </tr> <tr> <td>OR</td> <td> <ul style="list-style-type: none"> • RS (ODx[®]) >18 with cN 1 and non-pCR or • RS (ODx[®]) >25 with cN 0 and non-pCR </td> <td> <ul style="list-style-type: none"> • RS (ODx[®]) >18 with pN 1 or • RS (ODx[®]) >25 with pN 0 </td> </tr> <tr> <td>OR</td> <td colspan="2"> <ul style="list-style-type: none"> • high risk by PROSIGNA[®] (score > 60 in N 0 and > 40 in N +) or EPclin[®] (Score >3.3287), or MammaPrint[®] within clinical routine </td> </tr> <tr> <td>Intermediate clinical and unknown genomic risk</td> <td> <ul style="list-style-type: none"> • luminal-B-like tumor (G3 and/or Ki-67 pre-treatment ≥ 20%), AND • cN 1 with RS >18 (ODx[®]) and non-pCR, or • cN 0 with RS >25 (ODx[®]) and non-pCR </td> <td> <ul style="list-style-type: none"> • pN 1 with RS >18 (ODx[®]) or • pN 0 with RS >25 (ODx[®]) </td> </tr> </tbody> </table> <p> o if RS (ODx[®]) ≤25 in c/pN 0, o or RS (ODx[®]) ≤18 in c/pN 1 → ADAPTlate Non-High Risk → Endocrine Therapy at Investigator's Choice </p>		After neoadjuvant chemotherapy	After adjuvant treatment (chemotherapy and/or ET)	Known high clinical risk	<ul style="list-style-type: none"> • (cN 2-3 with pCR or non-pCR) or ypN 2-3 or • (cN 1 or G3 tumor and non-pCR) or ypN1 	<ul style="list-style-type: none"> • pN 0-1 and G3 with Ki-67 pre-treatment > 40% or • pN 0-1 and high CTS5 score or • pN 2-3 	OR	<ul style="list-style-type: none"> • RS (ODx[®]) >18 with cN 1 and non-pCR or • RS (ODx[®]) >25 with cN 0 and non-pCR 	<ul style="list-style-type: none"> • RS (ODx[®]) >18 with pN 1 or • RS (ODx[®]) >25 with pN 0 	OR	<ul style="list-style-type: none"> • high risk by PROSIGNA[®] (score > 60 in N 0 and > 40 in N +) or EPclin[®] (Score >3.3287), or MammaPrint[®] within clinical routine 		Intermediate clinical and unknown genomic risk	<ul style="list-style-type: none"> • luminal-B-like tumor (G3 and/or Ki-67 pre-treatment ≥ 20%), AND • cN 1 with RS >18 (ODx[®]) and non-pCR, or • cN 0 with RS >25 (ODx[®]) and non-pCR 	<ul style="list-style-type: none"> • pN 1 with RS >18 (ODx[®]) or • pN 0 with RS >25 (ODx[®])
	After neoadjuvant chemotherapy	After adjuvant treatment (chemotherapy and/or ET)														
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OR	<ul style="list-style-type: none"> • RS (ODx[®]) >18 with cN 1 and non-pCR or • RS (ODx[®]) >25 with cN 0 and non-pCR 	<ul style="list-style-type: none"> • RS (ODx[®]) >18 with pN 1 or • RS (ODx[®]) >25 with pN 0 														
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Einschluss- kriterien (Auswahl)	<ul style="list-style-type: none"> o Weiblich, prä- und postmenopausal o ER pos. und/ oder PR pos. Brustkrebs o HER2 neg. IHC Status 0, 1+, 2+ mit neg. SISH o Klinisches, genomisches oder intermediäres Risiko (siehe Studiendesign) o Ein bis sechs Jahre nach Start der endokrinen Therapie 															
Ausschluss- kriterien (Auswahl)	<ul style="list-style-type: none"> o Fernmetastasen o Vortherapie mit CDK4/6 o Maligne Vorgeschichte <5 Jahre 															

**Teilnehmende
Zentren**

- KEM Essen
- Uni Essen
- UKM Brustzentrum Münster
- Marien Hospital Witten
- GynOnco DUS
- Helios Wuppertal