

<b>Studiename</b>	<b>ADAPTlate</b> <b>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</b>															
<b>Sponsor/ Studiencode</b>	WSG WSG-AM11															
<b>Setting</b>	HR pos. HER2 neg. eBC, adjuvante Therapie															
<b>Primäres Studienziel</b>	Invasives DFS															
<b>Studiendesign</b>	<table border="1" data-bbox="427 831 1007 1305"> <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"> <li>• (cN 2-3 with pCR or non-pCR) or ypN 2-3 <b>or</b></li> <li>• (cN 1 or G3 tumor and non-pCR) or ypN1</li> </ul> </td> <td> <ul style="list-style-type: none"> <li>• pN 0-1 and G3 with Ki-67 pre-treatment &gt; 40% <b>or</b></li> <li>• pN 0-1 and high CTS5 score <b>or</b></li> <li>• pN 2-3</li> </ul> </td> </tr> <tr> <td>Known high genomic risk</td> <td> <ul style="list-style-type: none"> <li>• RS (ODx<sup>®</sup>) &gt;18 with cN 1 and non-pCR <b>or</b></li> <li>• RS (ODx<sup>®</sup>) &gt;25 with cN 0 and non-pCR</li> </ul> </td> <td> <ul style="list-style-type: none"> <li>• RS (ODx<sup>®</sup>) &gt;18 with pN 1 <b>or</b></li> <li>• RS (ODx<sup>®</sup>) &gt;25 with pN 0</li> </ul> </td> </tr> <tr> <td>OR</td> <td colspan="2"> <ul style="list-style-type: none"> <li>• high risk by PROSIGNA<sup>®</sup> (score &gt; 60 in N 0 and &gt; 40 in N +) or EPclin<sup>®</sup> (Score &gt;3.3287), or MammaPrint<sup>®</sup> within clinical routine</li> </ul> </td> </tr> <tr> <td>Intermediate clinical and unknown genomic risk</td> <td> <ul style="list-style-type: none"> <li>• luminal-B-like tumor (G3 and/or Ki-67 pre-treatment ≥ 20%), <b>AND</b></li> <li>• cN 1 with RS &gt;18 (ODx<sup>®</sup>) and non-pCR, <b>or</b></li> <li>• cN 0 with RS &gt;25 (ODx<sup>®</sup>) and non-pCR</li> </ul> </td> <td> <ul style="list-style-type: none"> <li>• pN 1 with RS &gt;18 (ODx<sup>®</sup>) <b>or</b></li> <li>• pN 0 with RS &gt;25 (ODx<sup>®</sup>)</li> </ul> </td> </tr> </tbody> </table> <p data-bbox="336 801 416 1429" style="border: 1px solid red; padding: 2px;">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> <div data-bbox="432 1317 1007 1429" style="border: 1px solid red; padding: 5px;"> <ul style="list-style-type: none"> <li>○ if RS (ODx<sup>®</sup>) ≤25 in c/pN 0,</li> <li>○ or RS (ODx<sup>®</sup>) ≤18 in c/pN 1</li> </ul> <p style="text-align: right; color: red; font-weight: bold;">ADAPTlate Non-High Risk</p> </div> <p data-bbox="1043 674 1497 1402">     Treatment Phase   FU-Phase      Years: Start, 1, 2, 3-6      Arm 1 N=602: ABEMACICLIB, Endocrine Therapy at Investigator's Choice (EOS)      Arm 2 N=301: Endocrine Therapy at Investigator's Choice (EOS)   </p>		After neoadjuvant chemotherapy	After adjuvant treatment (chemotherapy and/or ET)	Known high clinical risk	<ul style="list-style-type: none"> <li>• (cN 2-3 with pCR or non-pCR) or ypN 2-3 <b>or</b></li> <li>• (cN 1 or G3 tumor and non-pCR) or ypN1</li> </ul>	<ul style="list-style-type: none"> <li>• pN 0-1 and G3 with Ki-67 pre-treatment &gt; 40% <b>or</b></li> <li>• pN 0-1 and high CTS5 score <b>or</b></li> <li>• pN 2-3</li> </ul>	Known high genomic risk	<ul style="list-style-type: none"> <li>• RS (ODx<sup>®</sup>) &gt;18 with cN 1 and non-pCR <b>or</b></li> <li>• RS (ODx<sup>®</sup>) &gt;25 with cN 0 and non-pCR</li> </ul>	<ul style="list-style-type: none"> <li>• RS (ODx<sup>®</sup>) &gt;18 with pN 1 <b>or</b></li> <li>• RS (ODx<sup>®</sup>) &gt;25 with pN 0</li> </ul>	OR	<ul style="list-style-type: none"> <li>• high risk by PROSIGNA<sup>®</sup> (score &gt; 60 in N 0 and &gt; 40 in N +) or EPclin<sup>®</sup> (Score &gt;3.3287), or MammaPrint<sup>®</sup> within clinical routine</li> </ul>		Intermediate clinical and unknown genomic risk	<ul style="list-style-type: none"> <li>• luminal-B-like tumor (G3 and/or Ki-67 pre-treatment ≥ 20%), <b>AND</b></li> <li>• cN 1 with RS &gt;18 (ODx<sup>®</sup>) and non-pCR, <b>or</b></li> <li>• cN 0 with RS &gt;25 (ODx<sup>®</sup>) and non-pCR</li> </ul>	<ul style="list-style-type: none"> <li>• pN 1 with RS &gt;18 (ODx<sup>®</sup>) <b>or</b></li> <li>• pN 0 with RS &gt;25 (ODx<sup>®</sup>)</li> </ul>
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<b>Einschluss- kriterien (Auswahl)</b>	<ul style="list-style-type: none"> <li>○ Weiblich, prä- und postmenopausal</li> <li>○ ER pos. und/ oder PR pos. Brustkrebs</li> <li>○ HER2 neg. IHC Status 0, 1+, 2+ mit neg. SISH</li> <li>○ Klinisches, genomisches oder intermediäres Risiko (siehe <b>Studiendesign</b>)</li> <li>○ Ein bis sechs Jahre nach Start der endokrinen Therapie</li> </ul>															
<b>Ausschluss- kriterien (Auswahl)</b>	<ul style="list-style-type: none"> <li>○ Fernmetastasen</li> <li>○ Vortherapie mit CDK4/6</li> <li>○ Maligne Vorgeschichte &lt;5 Jahre</li> </ul>															

**Teilnehmende  
Zentren**

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