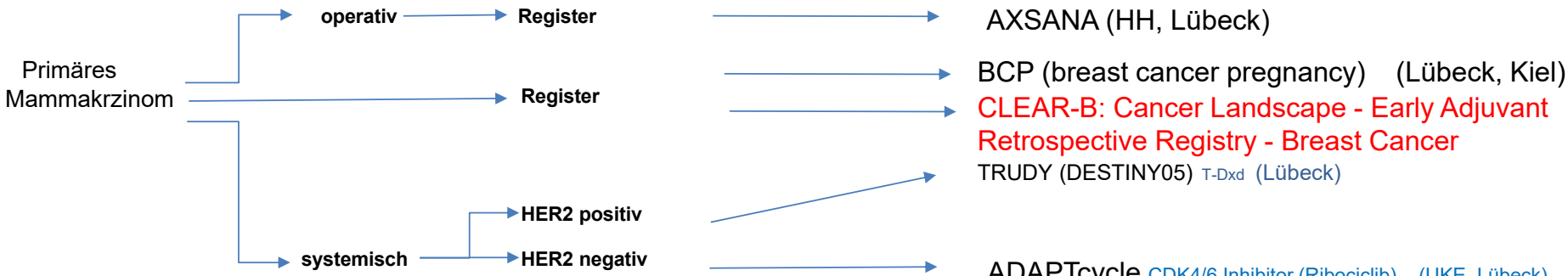
Gynäkologische Malignome und Mammakarzinom
Stand 02/2023

Unser Fahrplan

- Frühes und metastasiertes Mammakarzinom
- Ovarialkarzinom
- Zervixkarzinom
- Endometriumkarzinom
- Weitere gynäkologische Tumore

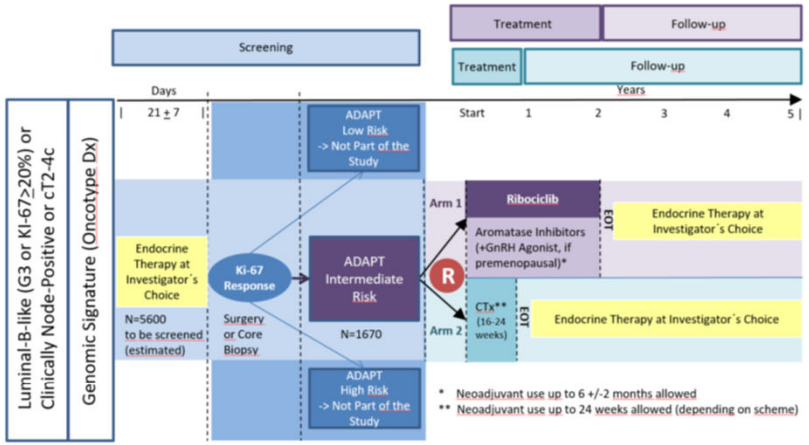
Studienbaum
Primäres Mamma-Ca

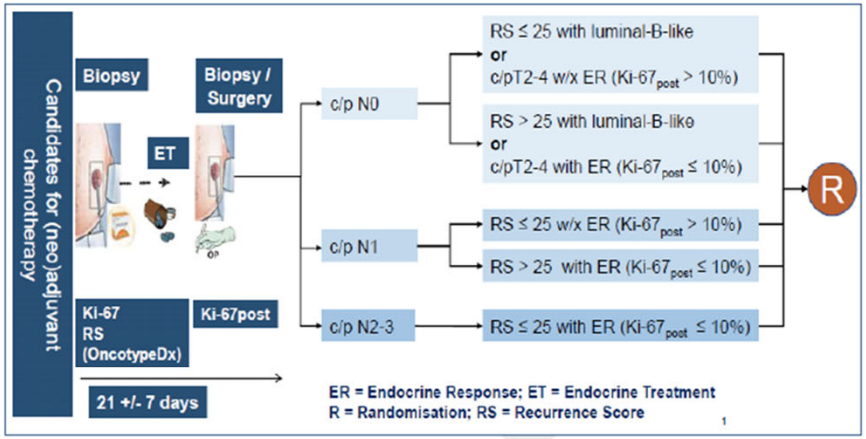


Mammakarzinom adjuvant
(HR positiv, HER2 negativ)

ADAPT CYCLE adjuvante Therapiemöglichkeit für Patientinnen mit HR+/HER2 negativem Mammakarzinom

Adjuvant Dynamic marker-Adjusted Personalized Therapy comparing endocrine therapy plus ribociclib versus chemotherapy intermediate risk HR+/HER2-early breast cancer





UKE, Lübeck

Studie UKE

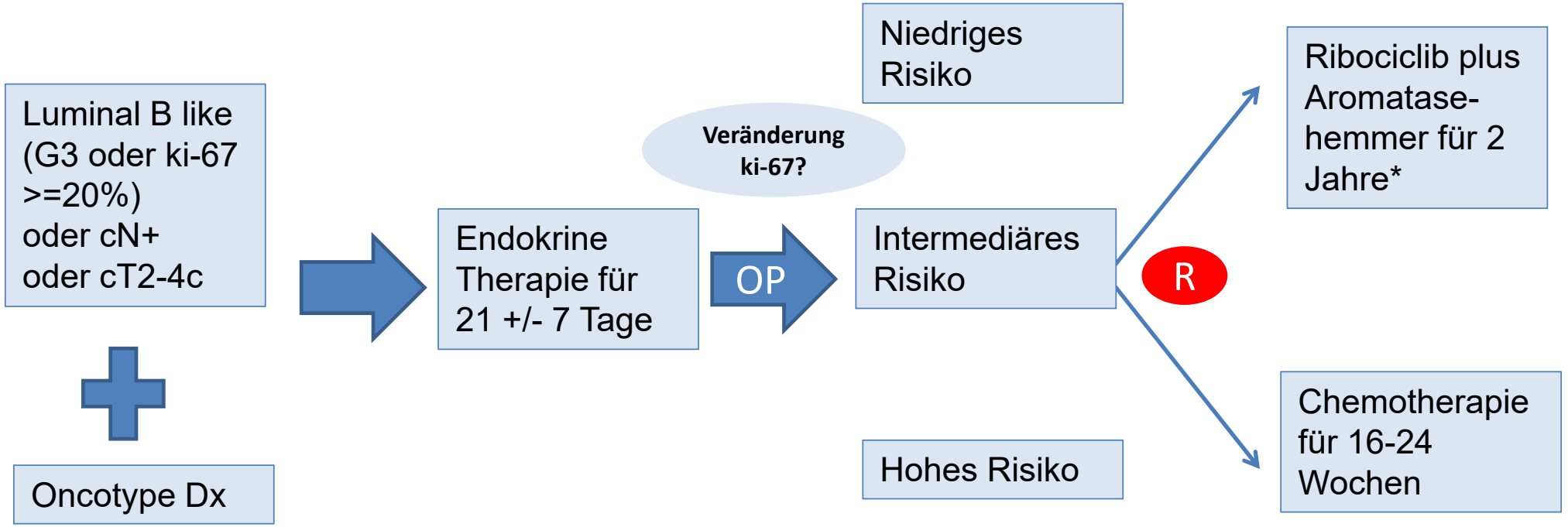
Adjuvant Dynamic marker - Adjusted Personalized Therapy comparing endocrine therapy plus ribociclib versus chemotherapy in intermediate risk, HR+/HER2- early breast cancer

Deutsche Übersetzung:

Adjuvante, auf dynamische Marker adjustierte, personalisierte Therapie zum Vergleich einer endokrinen Behandlung plus Ribociclib mit Chemotherapie bei Hormonrezeptor-positivem, HER2-Rezeptor negativem, mittleres Risiko aufweisendem, frühen Brustkrebs

Vergleich endokrine Therapie plus Ribociclib mit Chemotherapie bei Hormonrezeptor-positivem, HER2 negativem Mammakarzinom mit mittleren Risiko

Studie Adapt cycle (WSG)



* Operation nach ca. 6 Monaten, falls neoadjuvantes Regime

AXSANA

- Je nach Subtyp erreichen bis zu 60% der Frauen mit initial positivem Nodalstatus unter der neoadjuvanten Chemotherapie (NACT) eine pathologische Komplettremission (pCR) in der Axilla.
- Derzeit gibt es keinen klaren Standard für Patientinnen, die eine cN+ → ycN0 Konversion erreicht haben.
- Einerseits ist die Axilladissektion mit einer hohen Morbidität verbunden, die die langfristige Lebensqualität nachhaltig belasten kann, andererseits führt eine alleinige Sentinel node Biopsie in diesem Kollektiv zu hohen Falsch-Negativ-Raten.
- Die nationalen und internationalen Leitlinien bewerten die Datenlage nicht einheitlich, sodass derzeit weltweit unterschiedliche operative Verfahren eingesetzt werden.

Endpunkte:

iDFS, axilläre Rezidivrate, QoL

Stand 25.08.21:

20 Länder

878 Patientinnen rekrutiert

Target accrual 3000

www.axsana.eubreast.com

EUBREAST

AGO-B BREAST STUDY GROUP

AWOgyn

CLAUDIA VON SCHILLING FOUNDATION FOR BREAST CANCER RESEARCH

EHMANN-STIFTUNG SAVOGNIN

Karolinska Institutet

NOGGO e.V.

GBG GERMAN BREAST GROUP

endomag

MERITMEDICAL

Mammotome

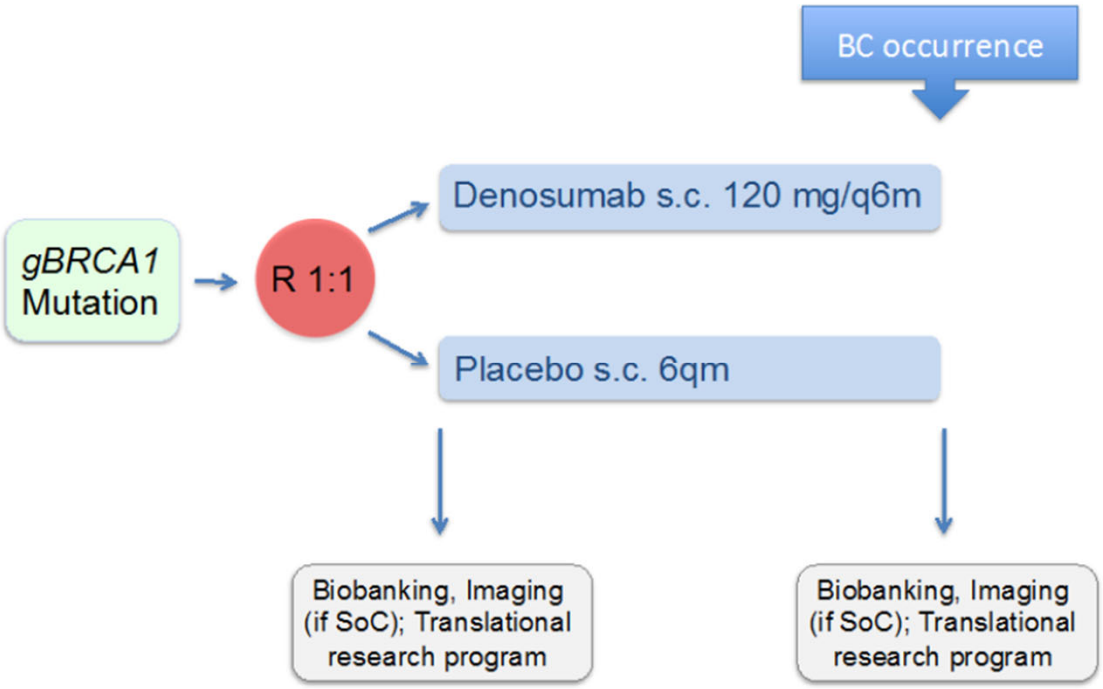
Hubertus Wald Tumorzentrum Universitäres Cancer Center Hamburg

Universitätsklinikum Hamburg-Eppendorf

BRCA-P (kommt)

Studie UKE

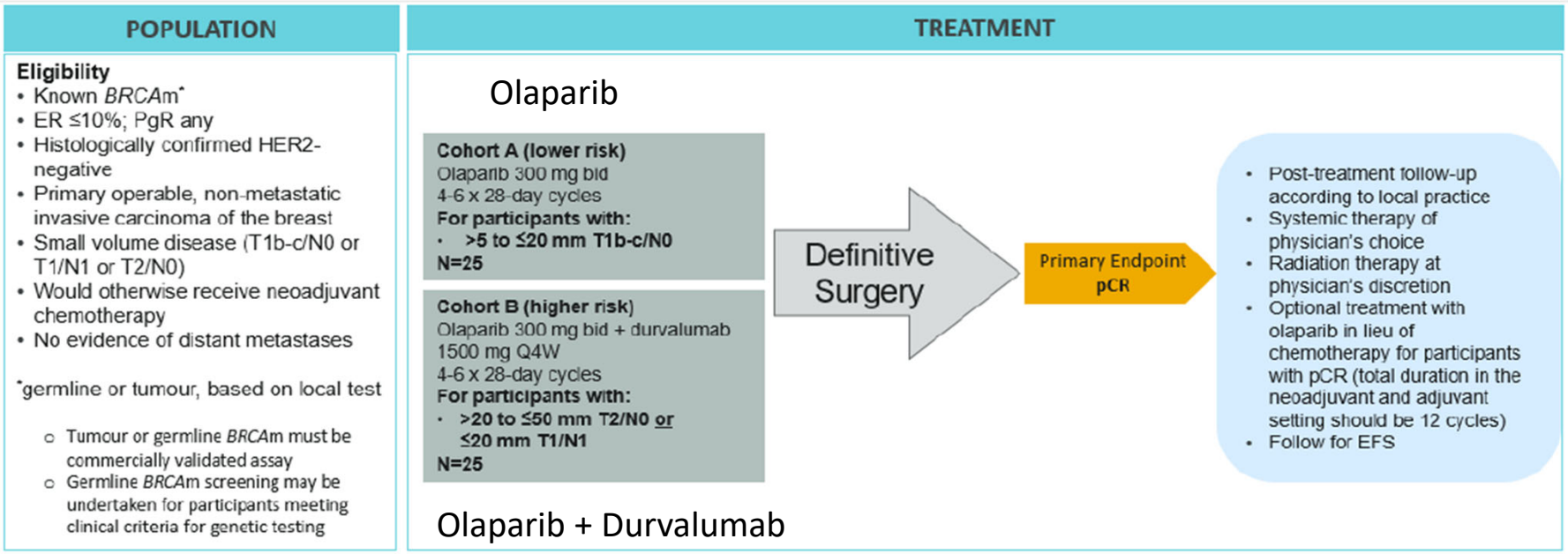
BRCA-P: A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, International Phase 3 Study to determine the Preventive Effect of Denosumab on Breast Cancer in Women carrying a *BRCA1* Germline Mutation



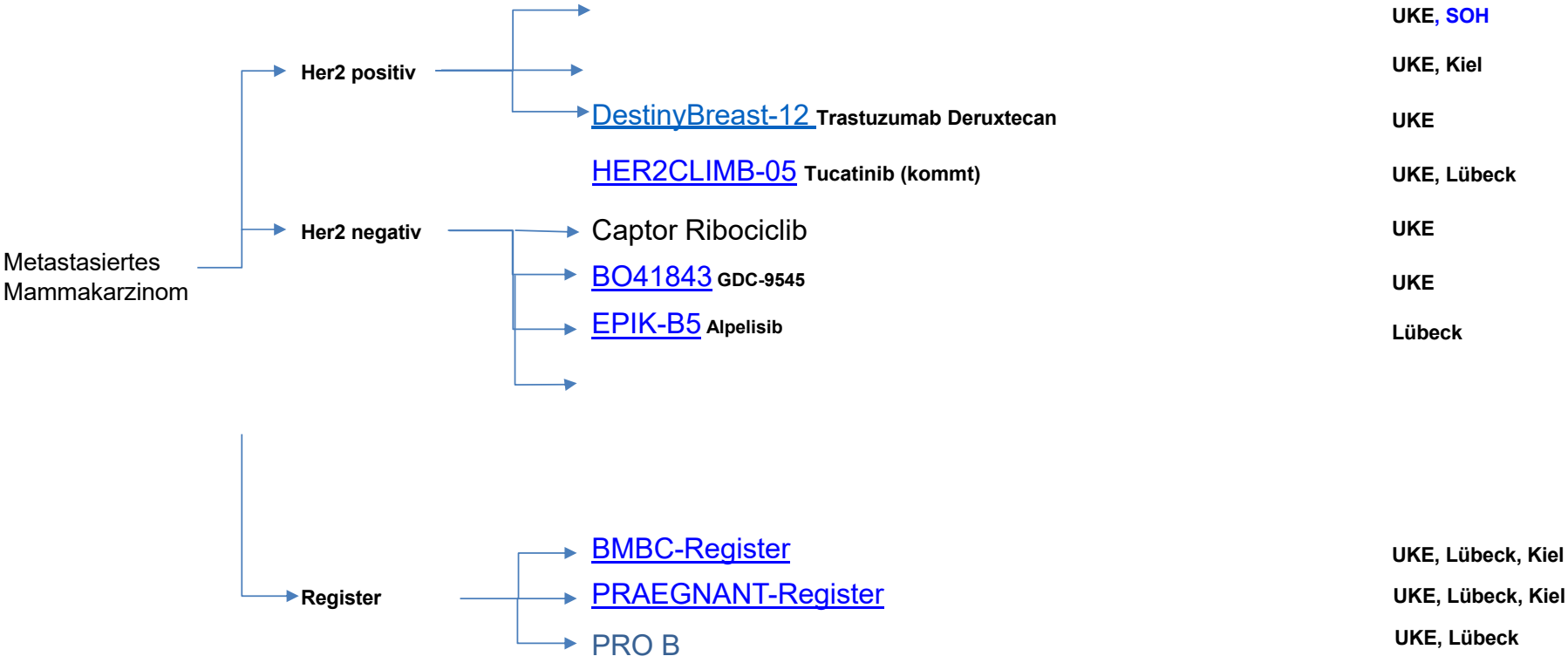
OlympiaN (kommt)

Studie UKE

A Phase II, Multicentre, Open-Label Study to Assess the Efficacy and Safety of Olaparib Monotherapy and Olaparib Plus Durvalumab Combination as Neoadjuvant Therapy in Patients with *BRCA* Mutations and Early Stage HER2-Negative Breast Cancer (OlympiaN)



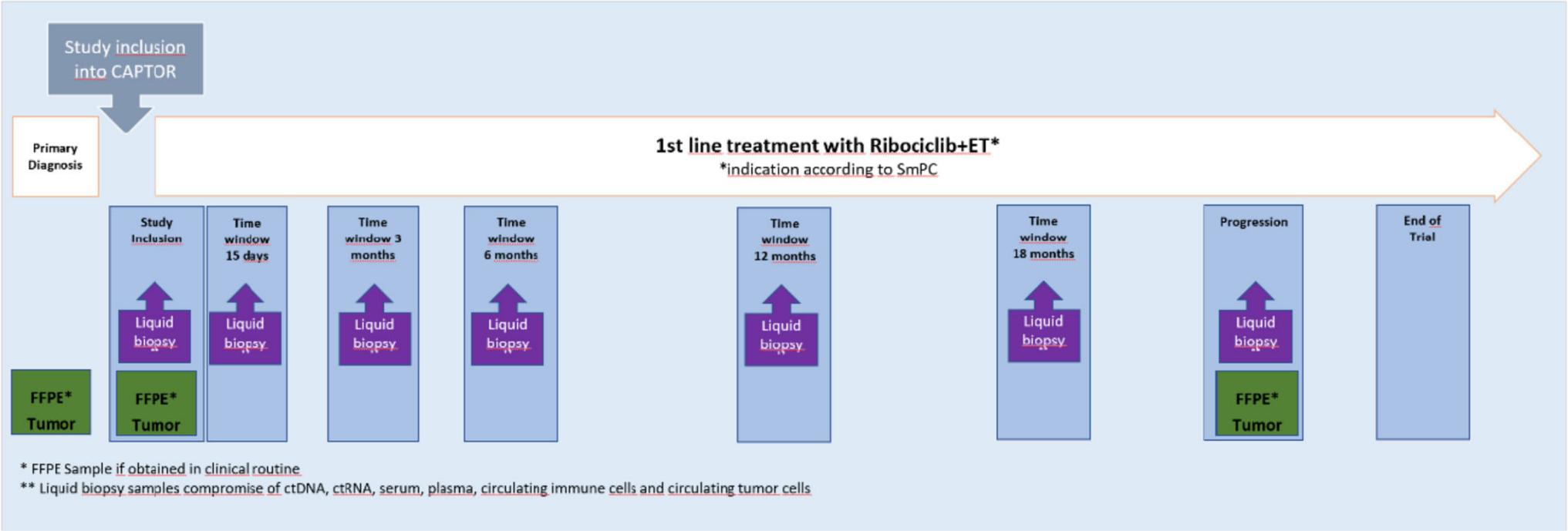
Studienbaum
Metastasiertes Mamma-Ca



Captor Biomarker Ribociclib

- N=1,000 metastastic first line breast cancer patients started on ribociclib
- Liquid biomarker panel testing at therapy begin and sequentially after therapy start
- FFPE testing at primary diagnosis, study inclusion and progression
- Comprehensive collection of digital data (histopathology, radiologic imaging, PROs)

- Co-Primary Aims: PFS and OS rates at months 12
- Secondary Aims: PFS, OS, Quality of life, Toxicity
- Exloratory Aims: Genomewide discovery and validation of genomic and big data biomarker

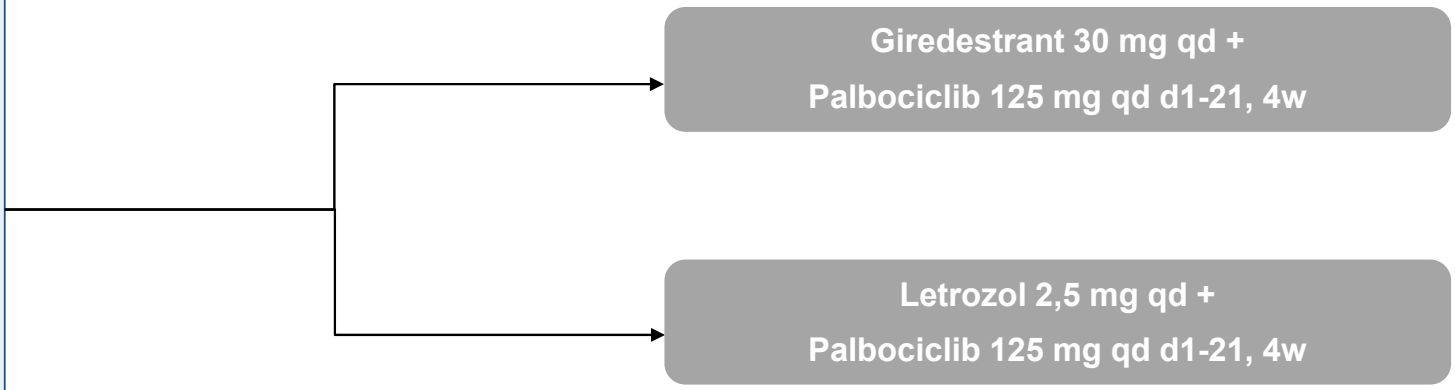


persevERA breast cancer (BO41843): Phase III Studie zur Wirksamkeit und Sicherheit von **Giredestrant** plus Palbociclib im Vergleich zu Letrozol plus Palbociclib beim HR+/HER2- mBC

HR+/HER2- lokal fortgeschritten oder metastasierter BC

- **Keine vorherige Therapie für die metastasierte/fortgeschrittene Situation**
- **Therapiefreiesintervall von mind. 12 Monaten nach Abschluß der (neo)adjuvanten AI-haltigen Therapie***
- **Keine vorherige SERD Therapie**
- **Keine aktive kardiale Erkrankung oder Anamnese einer kardialen Dysfunktion**

n=978



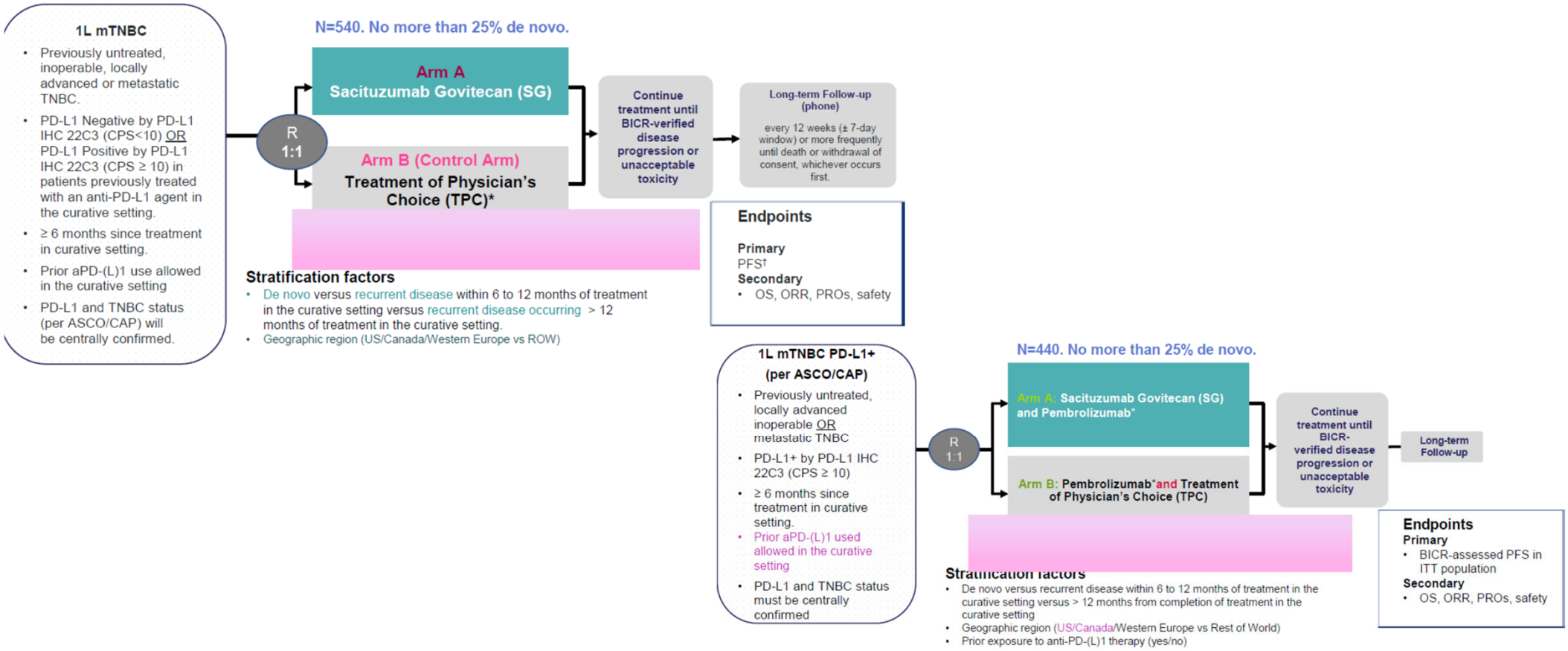
*Bei adjuvanter Tamoxifen-Therapie Therapiefreies-intervall mind. vor 24 Monate

Endpunkte:

- **Primärer Endpunkt: PFS (lokal bestimmt)**
- **Sekundäre Endpunkte: u. a. ORR, DOR, CBR, OS, PROs, Safety**

https://clinicaltrials.gov/ct2/show/NCT04546009

ASCENT 03 und 04: Sacitizumab Govitecan als Erstlinientherapie +/- Pembrolizumab



PHASE 3 STUDY OF TUCATINIB OR PLACEBO IN COMBINATION WITH TRASTUZUMAB AND PERTUZUMAB AS MAINTENANCE THERAPY FOR HER2+ METASTATIC BREAST CANCER (HER2CLIMB-05, TRIAL IN PROGRESS)

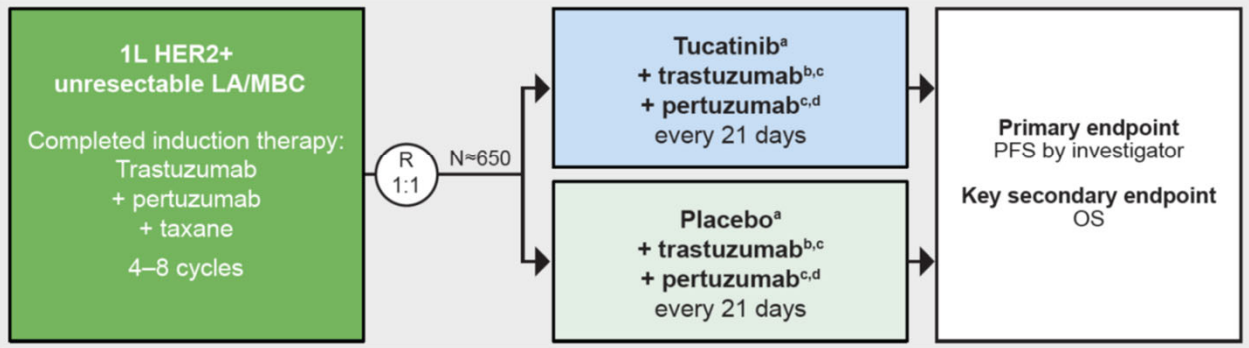
V. Müller[1], E. Hamilton[2], C. O'Sullivan[3], M. Martin[4], J. Sohn[5], K. Tryfonidis[6], L. Santarpia[7], S. Yang[8], V. Dieras[9]

[1]Universitätsklinikum Hamburg-Eppendorf, Hamburg, Deutschland; [2]Sarah Cannon Research Institute at Tennessee, Oncology, Nashville, TN, USA; [3]Vereinigte Staaten, Mayo Clinic, Rochester; [4]Vereinigte Staaten, Hospital General Universitario, Gregorio Marañón, Madrid, Spanien; [5]Yonsei Cancer Center, Seoul, Korea, Republik; [6]Merck & Co., Inc., Rahway, NJ, USA; [7]VereinigteStaaten; [8]Seagen Inc., Bothell, USA; [9]Vereinigte Staaten, Eugene Marquis Centre, Rennes, Frankreich

- Erhaltungstherapie Erstlinie HER2 positiv optimieren

Studie UKE

- HER2CLIMB-05 (NCT05132582) is a phase 3, randomized, double-blind study evaluating tucatinib or placebo in combination with trastuzumab plus pertuzumab as maintenance therapy in the 1L setting for patients with unresectable LA or metastatic HER2+ breast cancer following SOC induction therapy



Randomization will be stratified by diagnosis (de novo vs recurrent MBC), hormone receptor status (positive vs negative), and presence or history of BM (yes vs no)
[a]Tucatinib/placebo 300 mg will be administered PO from Cycle 1 Day 1 onward, BID on each day of study treatment. [b]IV trastuzumab will be given at a dose of 6 mg/kg once every 21 days. Alternatively, trastuzumab may be administered as an SC dose, at a fixed dose of 600 mg once every 21 days. SC trastuzumab does not require a loading dose. [c]A fixed dose of trastuzumab + pertuzumab (600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase) can be administered every 21 days by SC administration, in lieu of trastuzumab and pertuzumab administered IV individually. [d]Pertuzumab 420 mg will be administered every 21 days intravenously over 30-60 minutes.

HER2-positiv: DESTINY-Breast 12 mit TDx nach T-DM1 auch für Patientinnen mit Hirnmetastasen

Eligibility criteria

- Confirmed advanced or metastatic HER2-positive BC
- HER2 positivity per ASCO CAP Guidelines 2018
- Radiologic/objective evidence of disease progression on trastuzumab, pertuzumab, or T-DM1
  - *Prior tucatinib not permitted*
- ≤2 prior anti-HER2-based regimens in the metastatic setting
- ECOG PS 0–1
- LVEF ≥50% within 28 days before enrollment
- Patients with:
  - No evidence of BM
  - Untreated BM not needing immediate local therapy
  - Previously treated stable or progressing BM
- Provision of FFPE tumour sample
- At least one lesion ≥10 mm
- **EXCLUSION:** LMD

Cohort 1
No baseline BM
(n=250)

Target FPFV: April 2021

Cohort 2
Baseline BM
(untreated BMs[a] or previously treated stable or progressing BMs[b])
(n=250)

T-DXd[c]
5.4 mg/kg Q3W IV

Co-primary endpoints

Cohort 1 primary endpoint:
ORR by RECIST v1.1

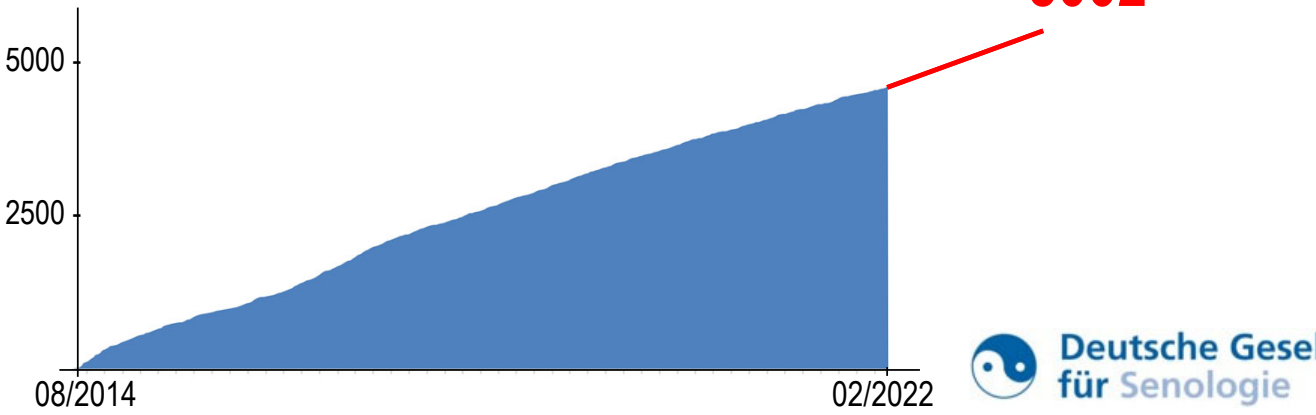
Cohort 2 primary endpoint:
PFS by RECIST v1.1

PRAEGNANT REGISTRY

Acknowledgements to the PRAEGNANT Steering-Board Committee

D. Wallwiener, H. Tesch, A. Schneeweiss, T. Fehm, W. Janni, P. Hadji, A. Hartkopf, HC Kolberg, D. Lüftner, M. P. Lux, F. Overkamp, F.-A. Taran, E. Belleville, J. Ettl, V. Müller, M. Wallwiener, S. Brucker, P. A. Fasching

- ongoing multicentric metastatic breast cancer registry
- 61 hospital and practices in Germany
- n = ~~4,704~~ **5002** patients

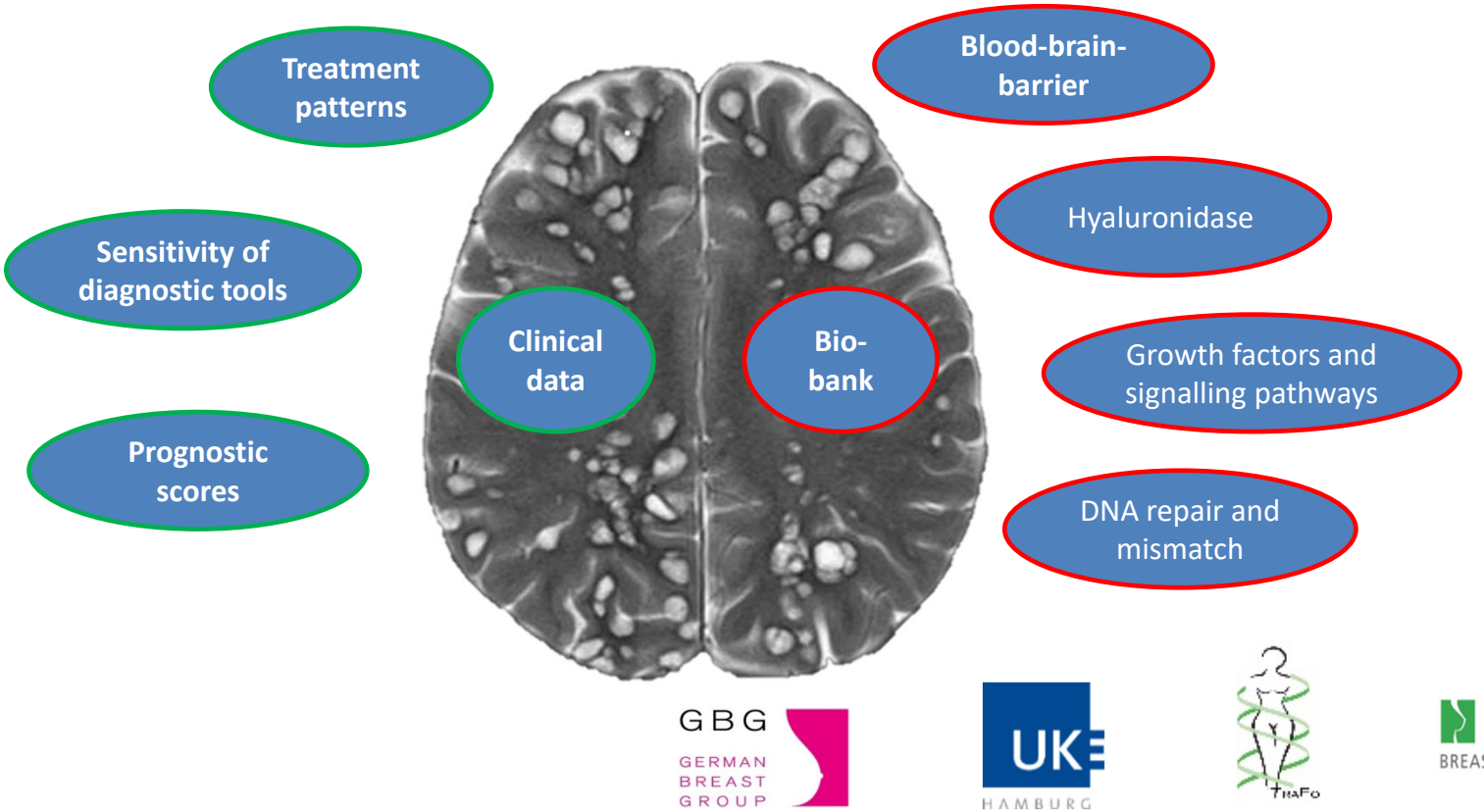


andreas.hartkopf@uniklinik-ulm.de

BrainMet-Register Deutschland Dezember 2022 (BMBC; GBG79)

- 163 Zentren registriert, 126 aktiv
- 4306 Patienten angelegt
- 3867 mit komplettem Datensatz

BrainMet-Register Deutschland Projekte (Auswahl)



GBG GERMAN BREAST GROUP

UKE HAMBURG

TRAFO

AGO-B BREAST STUDY GROUP

PRO-B

- multizentrische, zweiarmige, randomisiert-kontrollierte Interventionsstudie
- Evaluation der Auswirkungen eines intensivierten digitalen PRO-Monitorings auf die Lebensqualität und das Überleben von Patientinnen mit metastasiertem Mammakarzinom
- Konsortium

Ovarialkarzinom

Primäres Ovarialkarzinom → Systemtherapie → AGO-OVAR 28

NOGGO-ov53 – N-Plus

Ovarialkarzinom **Rezidiv** → Systemtherapie → AGO-OVAR 2.34 / MIROVA — P-sensibel

MITO-33 NItCHE trial — P-resistent

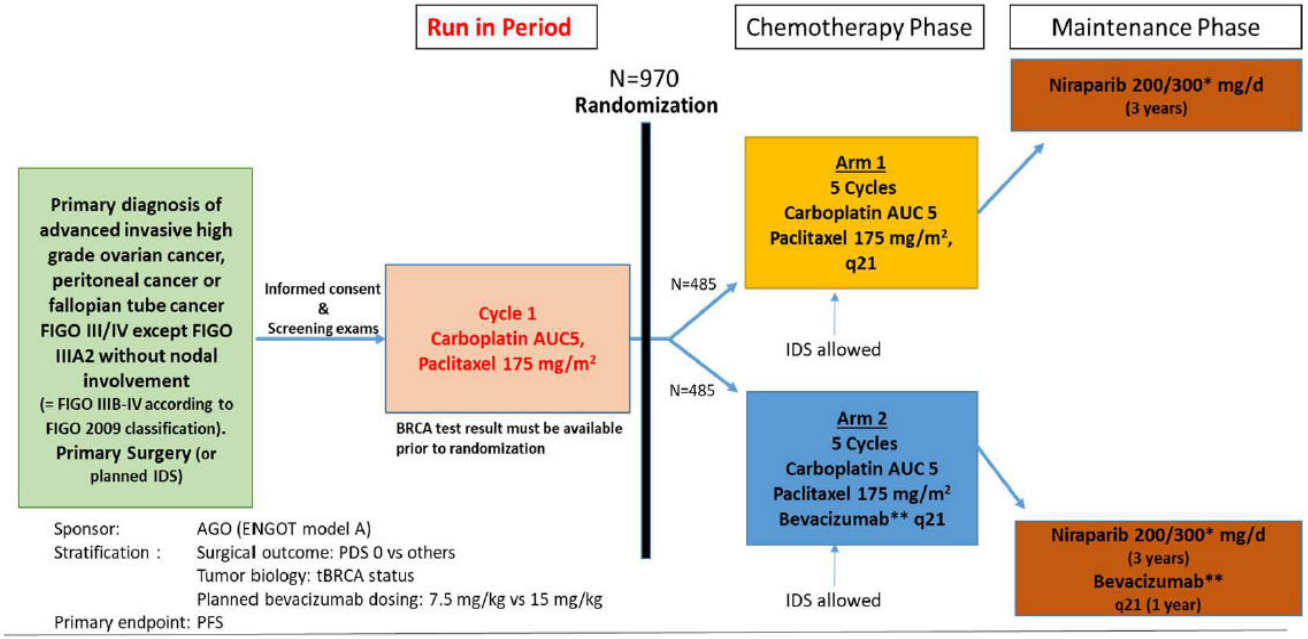
Maligner Keimzelltumor → Systemtherapie → NOGGO ov32 – MAKEI V

Niraparib vs Niraparib in combination with Bevacizumab in patients with carboplatinum-taxane based chemotherapy in advanced ovarian cancer (A multicentre randomised phase III trial)

ENGOT
European Network of Gynaecological Oncological Trial groups

AGO-OVAR 28 / ENGOT-ov57

Study Design



Sponsor: AGO (ENGOT model A)
Stratification : Surgical outcome: PDS 0 vs others
Tumor biology: tBRCA status
Planned bevacizumab dosing: 7.5 mg/kg vs 15 mg/kg
Primary endpoint: PFS

* The recommended starting dose of niraparib is 200 mg, taken once daily. For those patients who weigh ≥ 77 kg and have baseline platelet count ≥ 150,000/µL the recommended starting dose of niraparib is 300 mg, taken once daily.

** Bevacizumab dosing according to national standard (either 7.5 mg/kg or 15 mg/kg). In Germany, bevacizumab must be given at a dose of 15 mg/kg body weight at all participating study centers.
In patients with planned IDS, bevacizumab could be given before IDS according to local guidelines, but has to be omitted at the last cycle before IDS AND first cycle after IDS. Irrespective of the application of bevacizumab before IDS, bevacizumab should to be started 2 cycles after IDS. E.g. if IDS is planned after 3 cycles, bevacizumab should be omitted at cycle 3 and cycle 4 and could be started at cycle 5

Primary endpoint:
Progression Free Survival

Stratification:

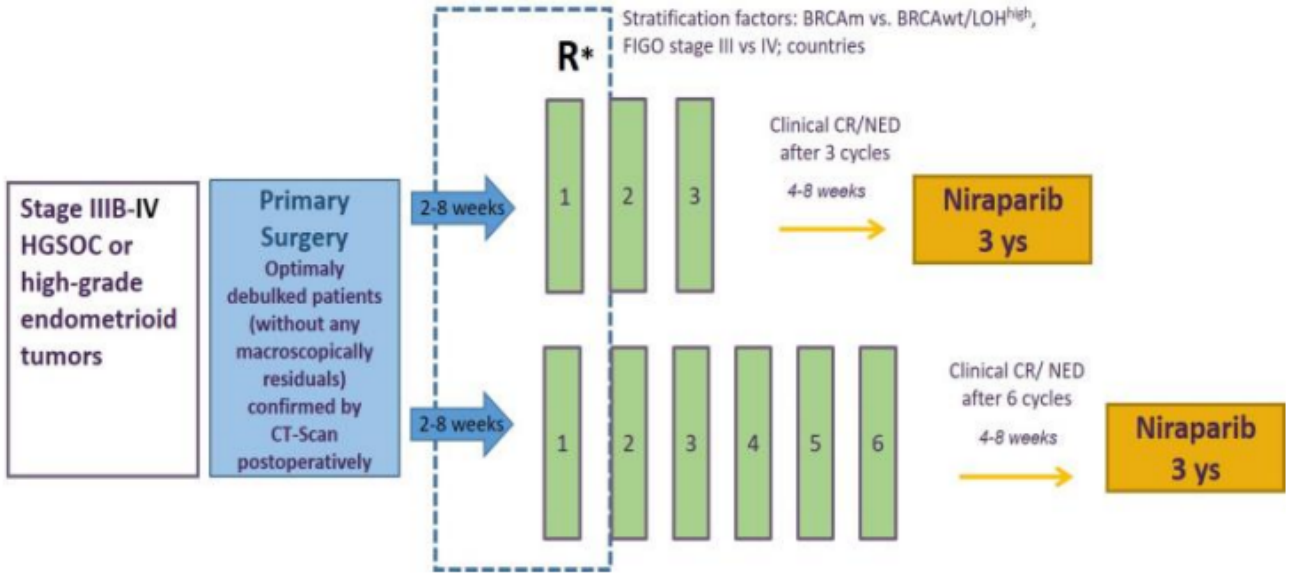
- Surgical outcome:
  Complete resection of all macroscopic tumor at primary debulking surgery (PDS 0) versus others
- Tumor biology - tBRCA status:
  Presence or absence of a deleterious/suspected deleterious tBRCA mutation
- Planned bevacizumab dosing:
  7.5 mg/kg or 15 mg/kg
  Of note, bevacizumab must be given at a dose of 15 mg/kg body weight at all participating study centers in Germany.

UKE

Hubertus Wald Tumorzentrum Universitäres Cancer Center Hamburg
Universitätsklinikum Hamburg-Eppendorf

NOGGO-ov53 – N-Plus

Randomized, open-label study of Niraparib Maintenance after Carboplatin and Paclitaxel in optimally debulked advanced HRD positive high grade ovarian cancer patients in first line therapy



* Die Standard-Chemotherapie muss innerhalb von 8 Wochen nach der primären Operation beginnen und kann vor der Randomisierung beginnen. Die Randomisierung muss spätestens am Tag C2D1 erfolgen.

Einschlusskriterien (Auswahl)

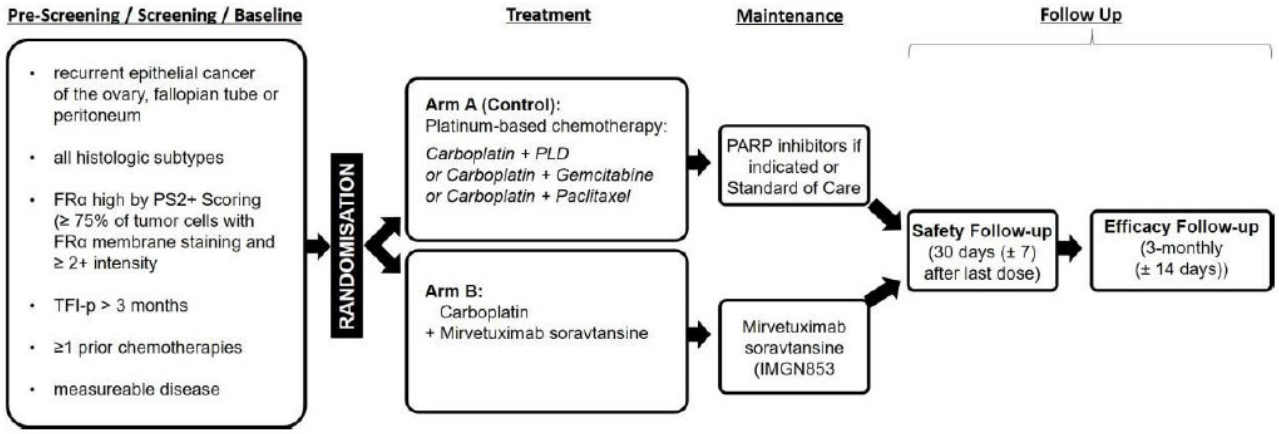
1. **FIGO Stage III-IV high-grade ovarian cancer (all histological types, except mucinous histology)**
2. Complete primary debulked patients (**without any macroscopic residuals**), confirmed by CT-Scan postoperatively
3. **Availability of archival tumor tissue for NGS Analysis**
4. Known BRCA Status
5. Postmenopausal Status, ECOG 0/1

Ausschlusskriterien (Auswahl)

1. **Endometrioid, clear-cell, germ-cell mucinous** histology, mixed tumours, low-grade/borderline ovarian tumor
2. Received any anti-cancer therapy for ovarian cancer other than primary surgery or undergone interval debulking of the tumor
3. Treatment with another PARPi in the past
4. Clinically significant cardiovascular disease
5. History or evidence of brain metastases/spinal cord compression

MIROVA: MIRvetuximab soravtansine in OVArian Cancer - AGO-OVAR 2.34

A randomized phase II trial of Mirvetuximab soravtansine (IMGN853), in folate receptor alpha (FRα) high recurrent ovarian cancer eligible for platinum-based chemotherapy.



Einschlusskriterien (Auswahl)

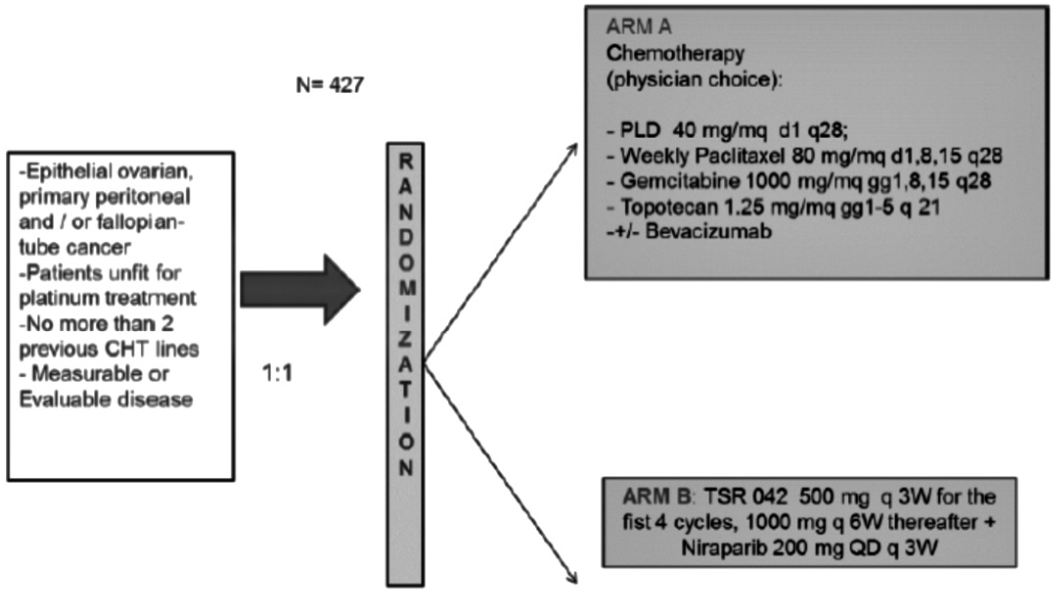
1. All patients must have a pathologically documented, definite diagnosis of epithelial cancer of the ovary, the fallopian tube or the peritoneum
2. Relapsed disease with a platinum-free interval > 3 months
3. All histologic subtypes of ovarian carcinoma including carcinosarcoma (malignant mixed Mullerian tumors, MMMT)
4. Patients with wildtype BRCA1/2 mutation status or with a deleterious BRCA1/2 mutation in germline or somatic testing if they underwent PARP inhibitor therapy in previous treatment.
5. Patients must be willing to provide archival tumor tissue from current relapse or previous surgeries/biopsies for central confirmation of FRα high status by PS2+ scoring: all tumors must exhibit ≥75% of tumor cells with FRα membrane staining and ≥ 2+ intensity by immunohistochemistry(IHC)
6. Patients must have measurable disease or evaluable disease in combination with GCIG CA-125 criteria.
7. Patients had one or more prior lines of chemotherapy. The last line of chemotherapy should have included platinum and has resulted in a partial or complete response.

Ausschlusskriterien (Auswahl)

1. Non-epithelial tumor origin of the ovary, the fallopian tube or the peritoneum (i.e. germ cell tumors)
2. Ovarian tumors of low malignant potential (e.g. borderline tumors)., unknown BRCA status.
3. Patients who are planned to receive bevacizumab for the current relapse, prior systemic anticancer therapy within 28 days before randomization,
4. Patients with > Grade 1 peripheral neuropathy.

MITO 33

Randomized phase III trial on Niraparib-TSR 042 vs physician's choice chemotherapy in recurrent, ovarian, fallopian tube or primary peritoneal cancer patients not candidate for platinum retreatment: MITO 33 trial



Stratification Factors:

- HRD status (HRD positive vs negative vs unknown)
- PDL 1 status (CPS > 10)
- Previous immunotherapy treatment
- Previous parp inhibitor treatment
- Bevacizumab treatment

PI/SI: Prof. Schmalfeldt/ Jaeger
StudyNurse: J. Granzow

Einschlusskriterien (Auswahl)

1. Participant must have recurrent ovarian, Fallopian tube or primary peritoneal cancer cancer not candidate for platinum retreatment; and in particular:
- platinum resistant patients (platinum-free interval 1-6 months from last dose of platinum)
- patients for which platinum is contraindicated because of previous allergic reactions or residual toxicity (i.e nephrotoxicity or neurotoxicity)
- patients not able (in physician's opinion) to receive further platinum or not willing (in patients' opinion) to receive further platinum
2. Participants must have measurable disease or evaluable based on RECIST 1.1 (patients with only CA 125 increase without evidence of disease are not included).
3. Participants must agree to provide tissue from a newly obtained core or excisional biopsy of a tumor lesion.

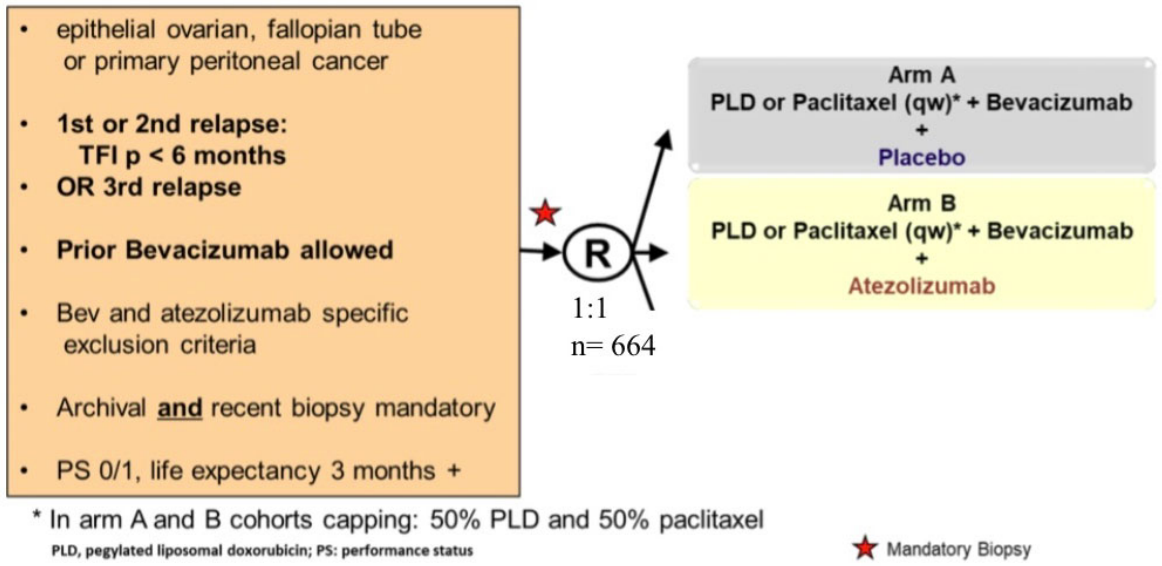
Ausschlusskriterien (Auswahl)

1.Participants have received >2 previous CHT lines (previous treatment with parp inhibitors and/or anti check point inhibitors is allowed providing that at least 6 months from last treatment are intercurred)
2. Participant has had radiation therapy encompassing >20% of the bone marrow within 2 weeks; or any radiation therapy within 1 week prior to Day 1 of protocol therapy.
3. Patient experienced ≥ Grade 3 immune-related AE with prior immunotherapy

Closed
IN FOLLOW-UP

AGO – Ovar 2.29

Randomisierte Phase III Studie zur Wirksamkeit und Sicherheit von Atezolizumab in Kombination mit Bevacizumab + Chemotherapie vs. Bevacizumab und Chemotherapie bei rezidiviertem Ovarialkarzinom.



Ergänzende Informationen sind unter ClinicalTrials.gov verfügbar

Einschlusskriterien (Auswahl)

- Histologisch gesichertes Ovarial-, Tuben- oder primares Peritonealkarzinom mit dem ersten oder zweiten
- Rezidiv innerhalb von 6 Monaten nach einer platinbasierten Chemotherapie oder dem dritten Rezidiv, wenn
- keine Platin-basierte Therapie in Frage kommt
- Vorherige Bevacizumab Therapie erlaubt (Auswaschphase: mind. 20 Tage nach der letzten Bevacizumab
- Therapie)
- Verfügbarkeit und Einwilligung fur frische Tumorbiopsie (nicht alter als 3 Monate) oder zugangliche Tumorläsion
- Reprasentative archivierte Tumorprobe (FFPE Block, bevorzugt von Primardiagnose)

Ausschlusskriterien (Auswahl)

- Nicht – epitheliale Ovarial-, Tuben – oder Peritonealkarzinome (z.B. Keimzelltumore)
- Ovarialtumore mit niedrigpotentem Potential (z.B. Borderline Tumore)
- Andere maligne Tumore in den letzten 5 Jahren
- Pat. mit Autoimmunerkrankungen (Ausnahmen: Autoimmun Hypothyreose, kontrollierter Typ I Diabetes mellitus)

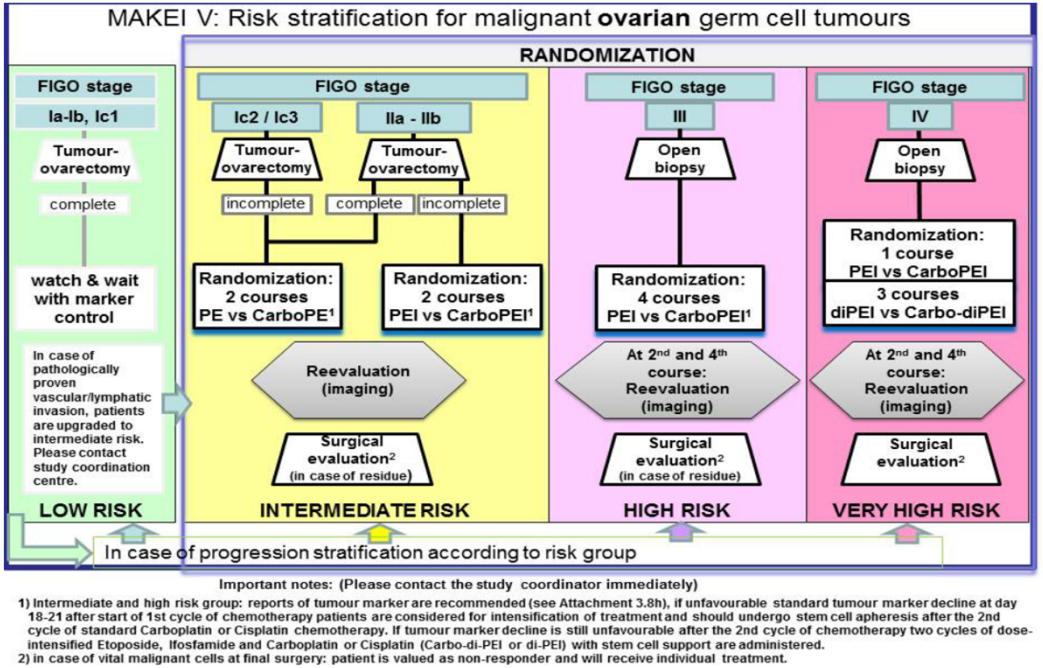
UKE,
Lübeck

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg

Universitätsklinikum
Hamburg-Eppendorf

NOGGO ov32 – MAKEI V

Prospective, multicentre phase III-trial in malignant extracranial germ cell tumours including a randomization between Carboplatin – and Cisplatin – combination standard chemotherapy based on a risk – stratification derived frm preceding MAKEI 96 trial and publised data



Important notes: (Please contact the study coordinator immediately)

1) Intermediate and high risk group: reports of tumour marker are recommended (see Attachment 3.8h), if unfavourable standard tumour marker decline at day 18-21 after start of 1st cycle of chemotherapy patients are considered for intensification of treatment and should undergo stem cell apheresis after the 2nd cycle of standard Carboplatin or Cisplatin chemotherapy. If tumour marker decline is still unfavourable after the 2nd cycle of chemotherapy two cycles of dose-intensified Etoposide, Ifosfamide and Carboplatin or Cisplatin (Carbo-di-PEI or di-PEI) with stem cell support are administered.
2) in case of vital malignant cells at final surgery: patient is valued as non-responder and will receive individual treatment.

Inclusion criteria

- Confirmed extracranial MGCT up to 17 11/12 years of age or patients with ovarian primaries up to 29 11/12 years of age on the date of written informed consent
- Diagnosis of a chemotherapy-naïve extracranial MGCT
- Karnofsky-Index of >70% or ECOG-Status 0-II
- Negative pregnancy test within 7 days prior to start of treatment for female patients of childbearing potential, in case of ß-HCG secreting MGCT pregnancy has to be excluded by appropriate methods

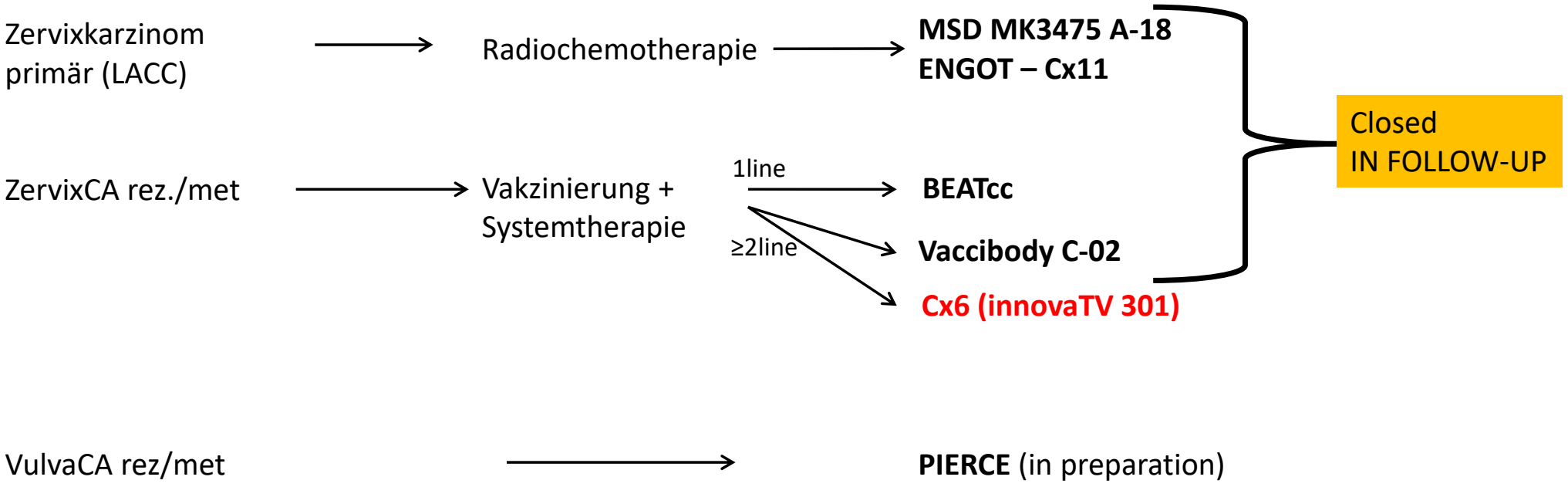
Exclusion criteria in general:

- Pregnancy, Lactation
- HIV-positivity
- Live vaccine immunization within two weeks before start of protocol treatment
- Sexually active adolescents not willing to use highly effective contraceptive method (pearl index <1) until 12 months after end of chemotherapy
- Any other medical, psychiatric or drug related condition, or social condition incompatible with protocol treatment.

Exclusion criteria in special indication:

- Second malignancies
- Negative preoperative tumour markers AFP and ß-HCG and solely pure teratoma histology
- Hearing impairment Grade 3 and 4 (CTCAE Vers.4.03)

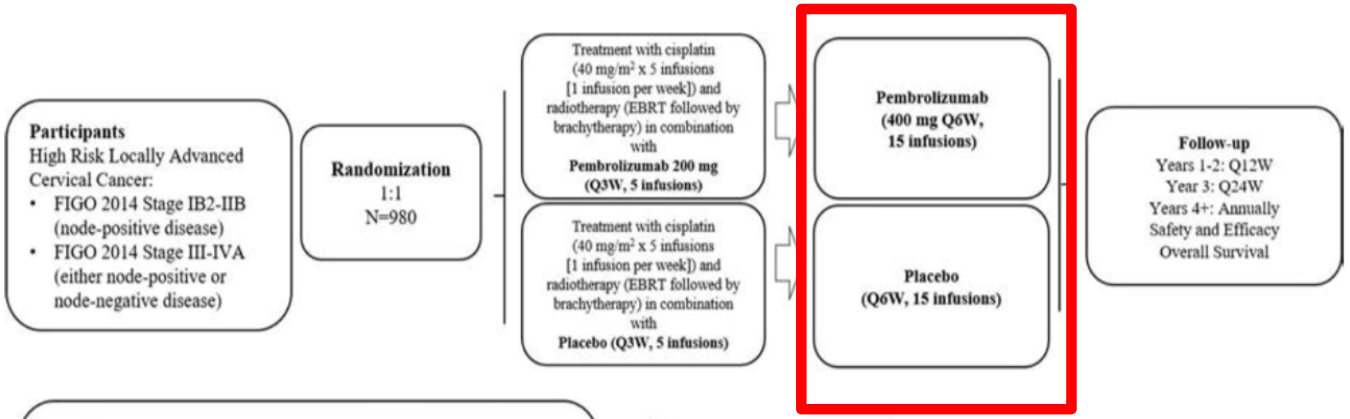
Zervix – und Vulvakarzinom



Closed
IN FOLLOW-UP

MSD-MK3475-A18 ENGOT – Cx11

Randomized, phase III, double-blinded study of chemoradiation with or without Pembrolizumab for the treatment of high – risk, locally advanced cervical cancer



UKE, Lübeck

Einschlusskriterien (Auswahl)

- high-risk LACC (a or b below):

a. FIGO 2014 Stage IB2-IIB (with node-positive disease)

b. b. FIGO 2014 Stages III-IVA (either node-positive or node-negative disease)

- not previously received any definitive surgical, radiation, or systemic therapy for cervical cancer and is immunotherapy-naïve. Note: Previous surgical procedure for localized cervical tumor is allowed.
- ECOG performance status of 0 or 1
- radiographically evaluable disease, either measurable or nonmeasurable per RECIST 1.1,
- tissue sample from a core or excisional biopsy of a tumor lesion for confirmation of adequacy
- adequate organ function

Ausschlusskriterien (Auswahl)

- histological subtypes other than those allowed (eg, sarcoma,small cell carcinoma with neuroendocrine differentiation, non-epithelial cancer).
- FIGO 2014 Stage IVB disease.
- previous hysterectomy defined as removal of the entire uterus or will have a hysterectomy as part of their initial cervical cancer therapy
- treatment with systemic immunostimulatory agents such as bacterial or viral vaccines, colony stimulating factors, interferons, interleukins and vaccine combinations
- prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (eg, CTLA-4, OX-40, CD137).

Closed
IN FOLLOW-UP

ENGOT-Cx10 / GEICO 68-C / JGOG1084 / GOG-3030 / BEATcc

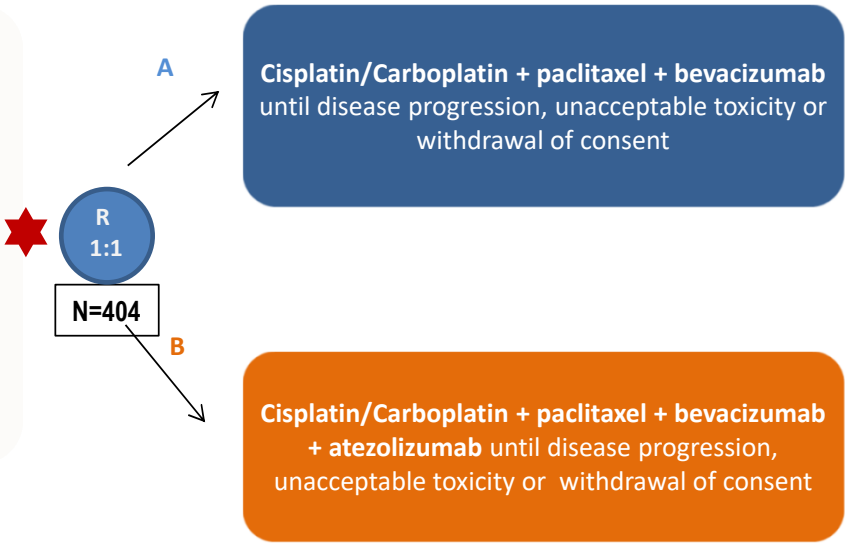
A Randomized Phase III Trial of Platinum Chemotherapy plus Paclitaxel with Bevacizumab and Atezolizumab versus Platinum Chemotherapy plus Paclitaxel and Bevacizumab in Metastatic (stage IVB), Persistent, or Recurrent Carcinoma of the Cervix

Eligibility Criteria:

- Persistent/Recurrent/metastatic cervical cancer
- ECOG PS 0/1
- No prior systemic anti-cancer therapy for metastatic or recurrent disease
- Available archival or fresh tumour for PD-L1 expression.

Stratification factors:

- Prior concurrent Cisplatin-RT
- Histology: SCC vs. ADK (including adenosquamous)
- Chemotherapy backbone (Cisplatin vs carboplatin)



Primary Endpoint:
PFS
OS
Secondary endpoint:
ORR
Safety
PRO/HRQoL

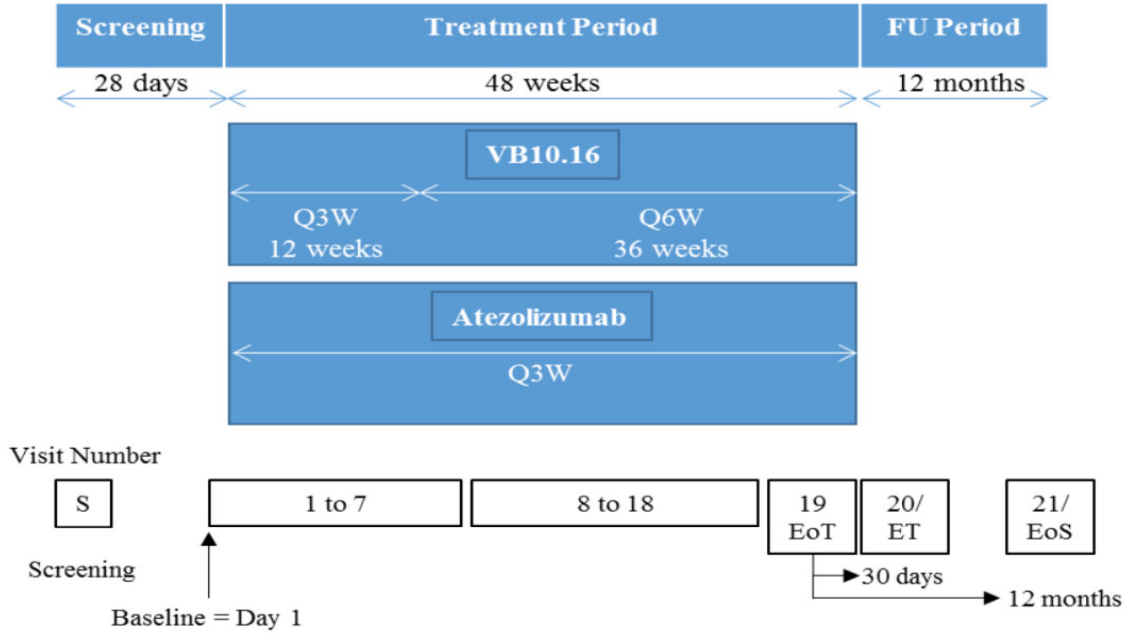
A tumour tissue biopsy collected within 3 months prior to study enrolment will be mandatory in the absence of an archival biopsy. Fine-needle aspiration, brushing, cell pellets from pleural effusion and lavage samples are not acceptable. For core needle biopsy specimens more than one core (if clinically feasible) should be submitted for evaluation. Retrieval of already available recent (withing 3 months prior to study enrolment) tumour sample can occur outside the 28 day screening period. Paired recent biopsies at baseline (lesion not previously irradiated; withing 3 months of randomization) and at progression disease will not be mandatory nevertheless they are encourage as long as these are feasible.

ClinicalTrials.gov Identifier: NCT03556839

Closed
IN FOLLOW-UP

Vaccibody C-02

Multi-Centre, open-label Phase IIa Trial of the Combination of VB10.16 and Atezolizumab in Patients with Advanced or Recurrent, Non-resectable HPV16-Positive Cervical Cancer



11 intramuscular (i.m.) vaccinations for up to 48 weeks from first vaccination. 5 vaccinations of 3 mg VB10.16 during the first 12 weeks, followed by vaccination every 6 weeks for up to 48 weeks + Atezolizumab (1200 mg) i.v. infusion every 3 weeks

UKE

Einschlusskriterien (Auswahl):

- persistent, recurrent, or metastatic non-resectable squamous cell carcinoma, adeno-squamous carcinoma, or adenocarcinoma of the cervix, not eligible for treatment with systemic CTX, radiotherapy or other standard-of-care anticancer treatment.
- HPV16 positive tumour. Provision of an archival tumour tissue sample not older than 2 years or new biopsy for analysing HPV16 status .
- a biopsy for PD L1 assessment at screening and measurable disease as assessed by the local site radiology as per RECIST 1.1.

Ausschlusskriterien (Auswahl)

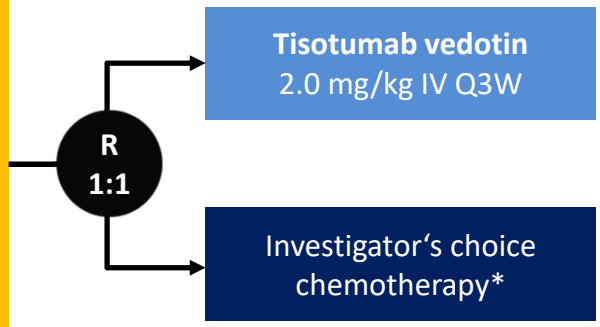
- prior treatment with CD137, anti-PD-1, or anti-PD-L1 therapeutic antibody or other immune checkpoint targeting agents
- concomitant or prior malignant disease, brain metastases, known or suspected autoimmune disease

ENGOT-cx12/GOG 3057/innovaTV 301
Study design

SGNTV-003: A Randomized, Open-Label, Phase 3 Trial of Tisotumab Vedotin vs Investigator's Choice Chemotherapy in Second- or Third-Line Recurrent or Metastatic Cervical Cancer

Key Eligibility Criteria

- Recurrent or metastatic cervical cancer
- Squamous cell, adenocarcinoma or adenosquamous histology
- Must have progressed during or after 1L SOC[a]
- Received 1 or 2 prior lines of chemotherapy doublet for recurrent and/or metastatic disease
- ECOG PS: 0 or 1



* IC chemotherapy:

- **Irinotecan**
- **Topotecan**
- **Gemcitabine**
- **Vinorelbine**
- **Pemetrexed**

Primary Endpoint

- Overall survival

Secondary Endpoints

- PFS (Inv)
- Confirmed ORR (Inv)
- DOR
- TTR
- Safety
- QoL[b]

Exploratory Endpoints

- TF expression (IHC or RNA)
- PK

Estimated enrollment: 482 participants

[a]Chemotherapy doublet or platinum doublet therapy with bevacizumab (if eligible); [b]Including EQ-5D-5L index, EQ-5D visual analog scale, EORTC-QLQ30, and EORTC-CX24.
1L, first-line; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IC, investigator's choice; IHC, immunohistochemistry; Inv, investigator-assessed; IV, intravenous; ORR, objective response rate; PFS, progression-free survival, PK, pharmacokinetics; Q3W, every 3 weeks; Qo,: quality of life; RNA, ribonucleic acid; SOC: standard of care; TF, tissue factor; TTR, time to response; TV, tisotumab vedotin.

VULVA-1 / PIERCE

Pembrolizumab in combination with lenvatinib in patients with recurrent, persistent, metastatic or locally advanced vulvar cancer not amenable to curative surgery or radiotherapy

- **Histologically confirmed locally advanced, recurrent, persistent and/or metastatic VSCC not amenable for salvage surgery or definitive (chemo)radiation**
- Measurable disease (RECIST 1.1)
- ECOG 0–1
- Up to 2 prior chemotherapy lines
- Available archival+/fresh tumour tissue

N=42

Lenvatinib 20mg QD

Pembrolizumab 400mg IV q6w (max 18 cycles)

to PD by RECIST 1.1 / toxicity

Tumor assessment every 8,16 and 24 weeks of treatment and thereafter every 12 weeks

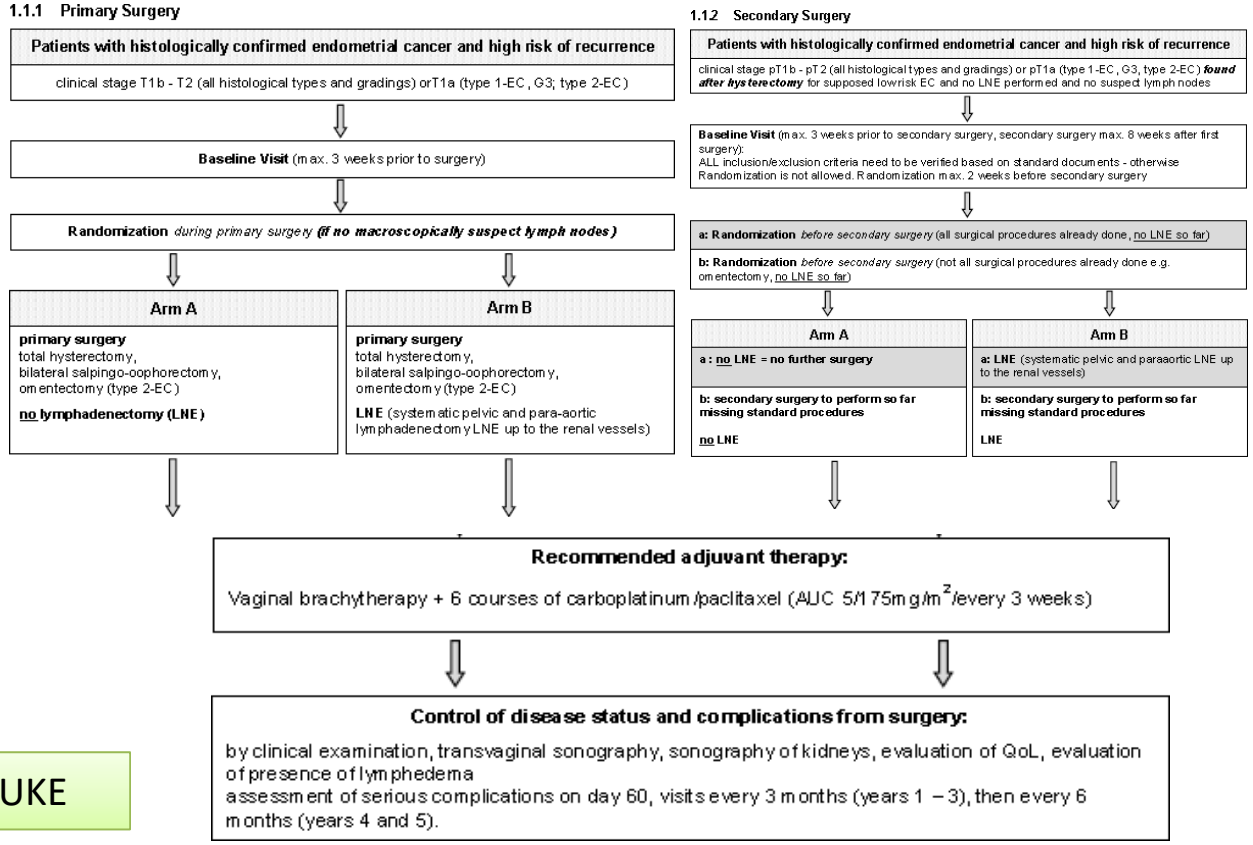
Primary endpoint: investigator-assessed ORR within 24 weeks evaluated by RECIST 1.1
Secondary endpoints: Overall ORR, DCR, DOR, OS, PFS, TFST, TSST, safety and health-related QoL

Endometriumkarzinom

Primäres Endometriumkarzinom → operativ → **AGO-OP 6 ECLAT**

AGO – OP 6 – ECLAT

Pelvine und paraaortale Lymphadenektomie bei Patientinnen mit Endometriumkarzinom Stadium I oder II mit hohem Rezidivrisiko. Eine multizentrische, prospektive randomisierte kontrollierte Studie.



UKE

Einschlusskriterien (Auswahl)

- Histologisch gesichertes EC T1b und T2 (alle histolog. Typen) und Stadium T1a G3 Typ 1 oder Typ 2
- Tumore oder Karzinosarkom.
- a) keine vorhergehende Operation bezgl. Des EC (primare Operation) **oder**
- b) Operation nach Hysterektomie ist erlaubt innerhalb von 8 Wochen nach Hysterektomie, wenn
- keine LNE erfolgt ist (sekundare Operation).
- Keine vergroserten Lymphknoten
- ECOG 0-1
- Alter 18 - 75

Ausschlusskriterien (Auswahl):

- Stadium pT1a, G1 oder G2 mit Typ 1 Histologie
- Sakome (mit Ausnahme Karzinosarkome = maligen Mullersche Mischtumore)
- EC FIGO Stadium III oder IV (auser mikroskopische Lymphknotenmetastasen)
- Nachweis einer extrauterinen Erkrankung
- Rezidivierendes EC
- Vorangegangene Chemo-, Radio-, oder endokrine Therapie fur EC
- Jede Begleiterkrankung, die eine Operation einschlieslich LNE und/oder Chemotherapie nicht
- zulasst
- Jede Krankengeschichte, die auf ein ubermasiges perioperatives Risiko hinweist.