Gynäkologische Malignome und Mammakarzinom

Trial Finder Stand 06/2024

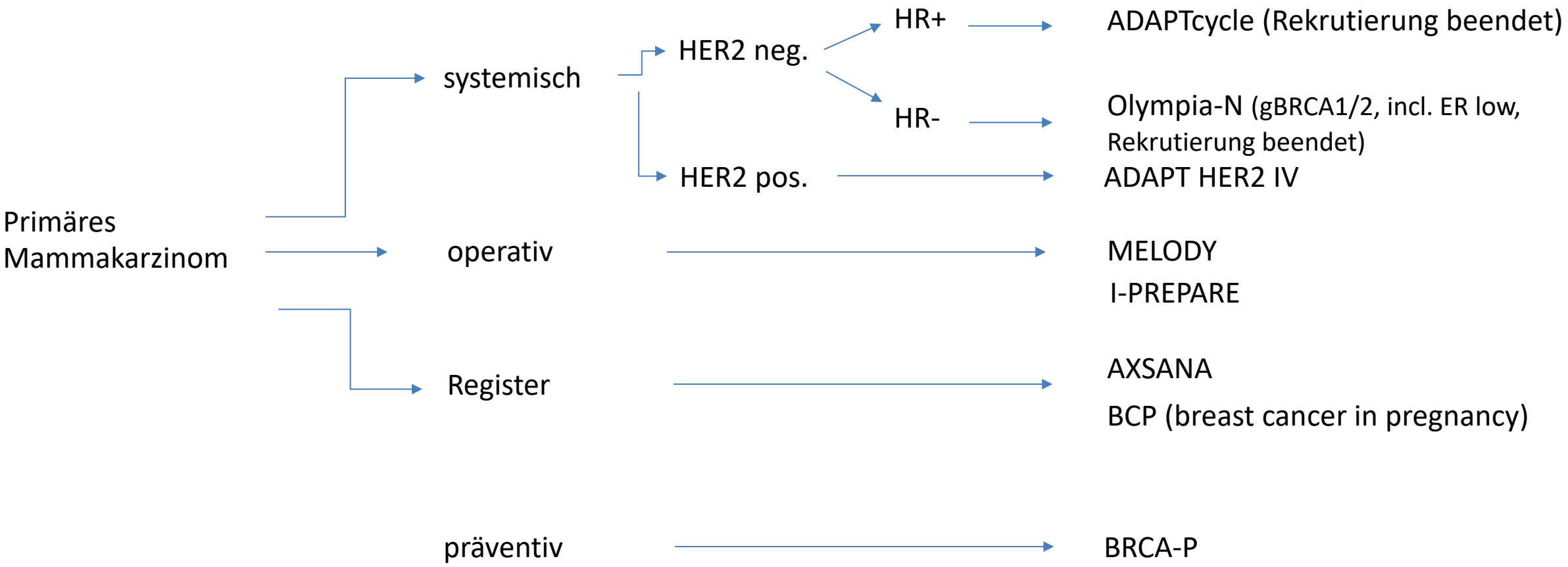
Unser Fahrplan

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

Frühes und metastasiertes Mammakarzinom

Studienbaum

Primäres Mammakarzinom



OlympiaN

REKRUTIERUNG BEENDET

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)

POPULATION

Eligibility

- Known *BRCA*m*
- ER ≤10%; PgR any
- Histologically confirmed HER2-negative
- Primary operable, non-metastatic invasive carcinoma of the breast
- Small volume disease (T1b-c/N0 or T1/N1 or T2/N0)
- Would otherwise receive neoadjuvant chemotherapy
- No evidence of distant metastases

*germline or tumour, based on local test

  - Tumour or germline *BRCA*m must be commercially validated assay
  - Germline *BRCA*m screening may be undertaken for participants meeting clinical criteria for genetic testing

TREATMENT

Olaparib

Cohort A (lower risk)
Olaparib 300 mg bid
4-6 x 28-day cycles
For participants with:
- **>5 to ≤20 mm T1b-c/N0**

N=25

Cohort B (higher risk)
Olaparib 300 mg bid + durvalumab
1500 mg Q4W
4-6 x 28-day cycles
For participants with:
- **>20 to ≤50 mm T2/N0 or ≤20 mm T1/N1**

N=25

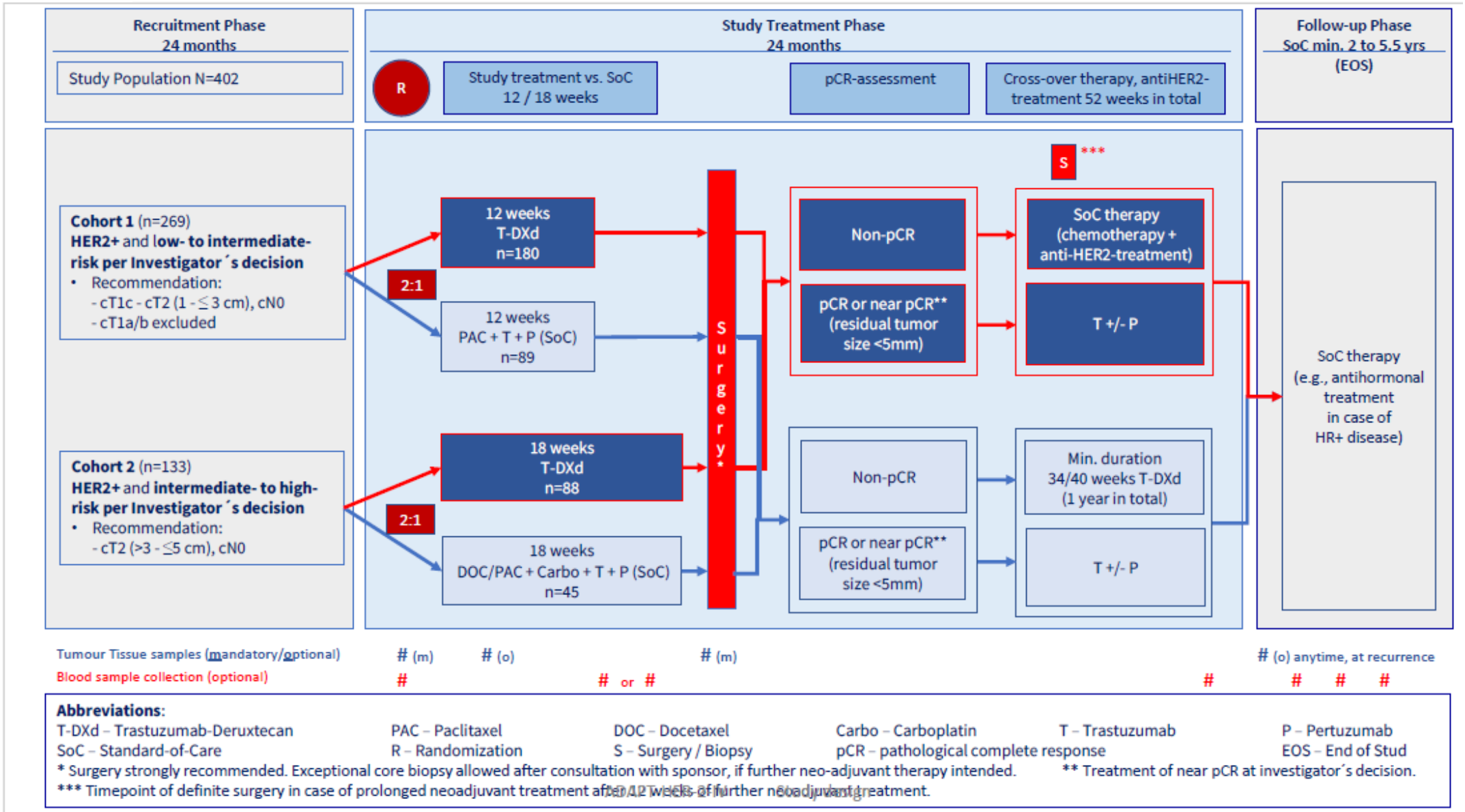
Olaparib + Durvalumab

Definitive Surgery

Primary Endpoint pCR

- Post-treatment follow-up according to local practice
- Systemic therapy of physician's choice
- Radiation therapy at physician's discretion
- Optional treatment with olaparib in lieu of chemotherapy for participants with pCR (total duration in the neoadjuvant and adjuvant setting should be 12 cycles)
- Follow for EFS

Neo*A*djuvant *D*ynamic marker - *A*djusted *P*ersonalized *T*herapy comparing trastuzumab-deruxtecan versus paclitaxel+/-carboplatin+trastuzumab+pertuzumab in HER2+ early breast cancer (ADAPT-HER2-IV



Abbreviations:

T-DXd – Trastuzumab-Deruxtecan | PAC – Paclitaxel | DOC – Docetaxel | Carbo – Carboplatin | T – Trastuzumab | P – Pertuzumab

SoC – Standard-of-Care | R – Randomization | S – Surgery / Biopsy | pCR – pathological complete response | EOS – End of Stud

* Surgery strongly recommended. Exceptional core biopsy allowed after consultation with sponsor, if further neo-adjuvant therapy intended.

** Treatment of near pCR at investigator´s decision.

*** Timepoint of definite surgery in case of prolonged neoadjuvant treatment after 12 weeks of further neoadjuvant treatment.

MEthods for LOcalization of Different types of breast lesions

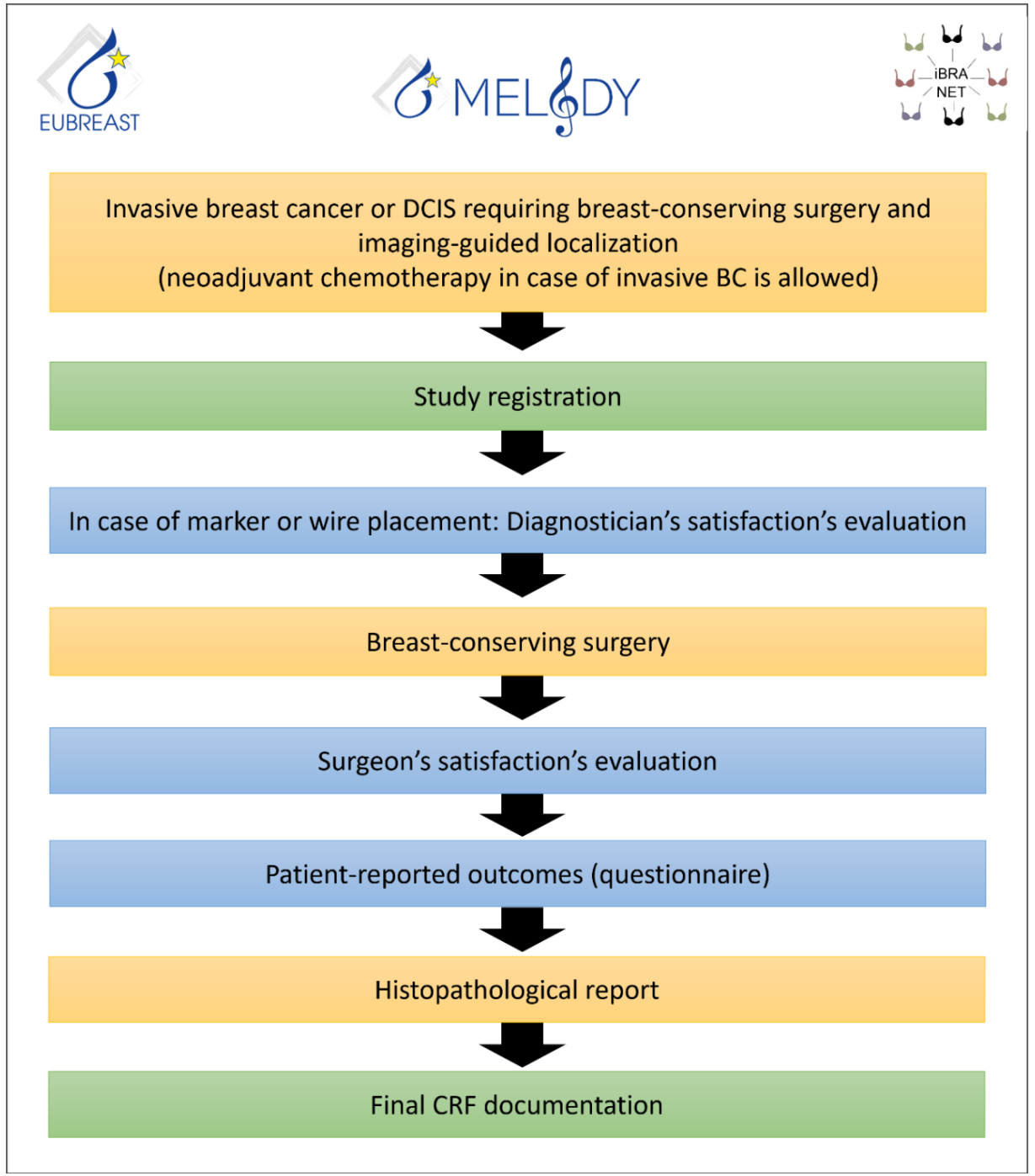
(EUBREAST 4)

Study design

- Non-interventional observational international prospective cohort study
- Investigator-initiated study

Aims and objectives

- Primary outcomes:
- - Intended target lesion and/or marker removal, independent of margin status on final histopathology
- - Negative resection margin rates (defined as lesion removal with no invasive or non-invasive carcinoma on ink) at first surgery


EUBREAST
MELODY
iBRA NET
Invasive breast cancer or DCIS requiring breast-conserving surgery and imaging-guided localization
(neoadjuvant chemotherapy in case of invasive BC is allowed)
Study registration
In case of marker or wire placement: Diagnostician's satisfaction's evaluation
Breast-conserving surgery
Surgeon's satisfaction's evaluation
Patient-reported outcomes (questionnaire)
Histopathological report
Final CRF documentation

International Prospective REgistry on Pre-pectorAl breast Reconstruction (I-PREPARE EUBREAST-11R)

- Study design

  International prospective cohort study

- Study aims Primary endpoint:

  Implant-loss at three months postoperatively defined as the unplanned removal or loss of the implant as a result of infection or other complication

AXSANA

REGISTER

- 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

BCP Breast cancer pregnancy

BCP
Breast Cancer in Pregnancy

Prospektive und Retrospektive Registerstudie der German Breast Group (GBG) zur Diagnostik und Therapie des Mammakarzinoms in der Schwangerschaft mit jungen, nicht schwangeren Patientinnen (<40 Jahre) als Vergleichskohorte

Einschlusskriterien
- Pat. mit histologisch gesichertem Mammakarzinom und Schwangerschaft oder
- Nicht-schwangere Patientin < 40 Jahre mit histologisch gesichertem Mammakarzinom
- Schriftliche Einwilligung für die Datenerhebung bei prospektiven Patientinnen
- Karnofsky-Index >80%
- Pat. geeignet für Operation u/o Chemotherapie
- Keine Pathologien des Schwangerschaftsverlaufes

GBG
GERMAN
BREAST
GROUP

BCP Breast cancer pregnancy

BCP
Breast Cancer in Pregnancy

Primärer Endpunkt:

Fetal outcome 4 Wochen nach Entbindung

Sekundäre Endpunkte

- Mütterliches outcome bezüglich der Schwangerschaft
- Stadium und biologische Eigenschaften des Mammakarzinoms
- Mamma-Karzinom-Therapie (Medikamente, Anprechen auf CHT, Op-Typ)
- Sensitivität und Spezifität der Diagnostik, klinische Untersuchung, Ultraschall, Mammographie, MRT
- Outcome des Neugeborenen nach Therapie
- Outcome des Mammakarzinoms nach Therapie
- Anzahl der Schwangerschaften nach Mammakarzinom
- Biologie des Tumors von schwangeren Patientinnen gemessen im Vergleich zu jungen nicht-schwangeren Frauen
- Alle Parameter werden mit jungen nicht-schwangeren Frauen verglichen

GBG
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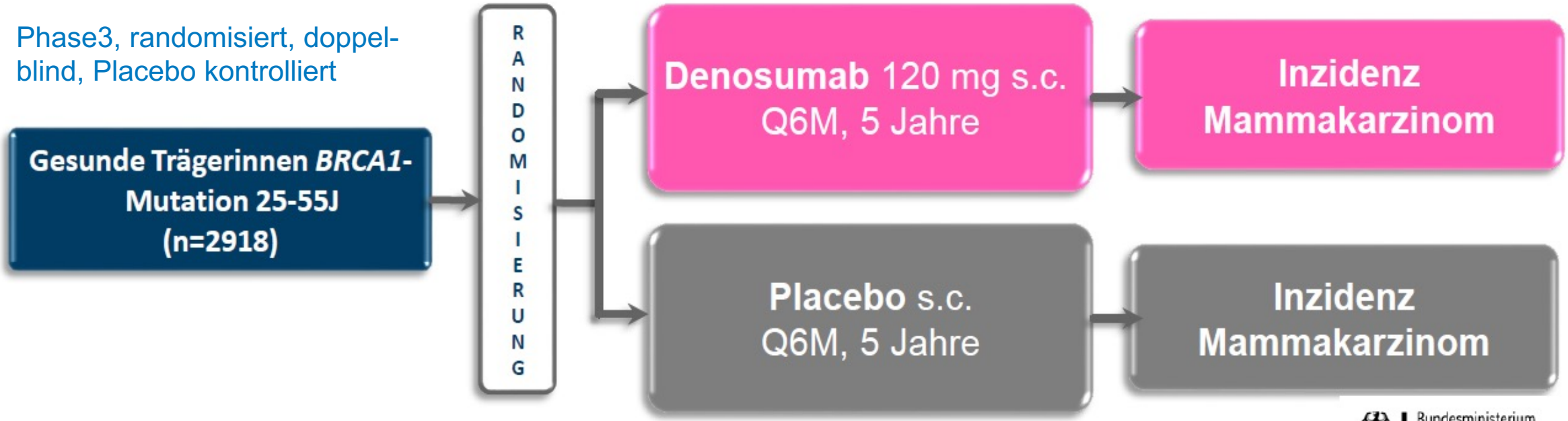
GROUP

BRCA-P

Phase3, randomisiert, doppel-blind, Placebo kontrolliert



Global Lead: Christian Singer, ABCSG
Deutschland: Rita Schmutzler, Kerstin Rhiem DK-FBEK

Förderung durch Bundesministerium für Bildung und Forschung

Primärer Endpunkt

- Zeit bis zum Auftreten von Brustkrebs (invasiv/DCIS)

Sekundäre Endpunkte

- Zeit bis invas. Brustkrebs, Zeit bis TNBC, Zeit bis Ovarialkarzinom, Zeit bis zu anderen Malignomen, Frakturen bei prä-/postmenopausalen Frauen, Häufigkeit von Stanzbiopsien der Mamma

BRCA-P

Einschlusskriterien

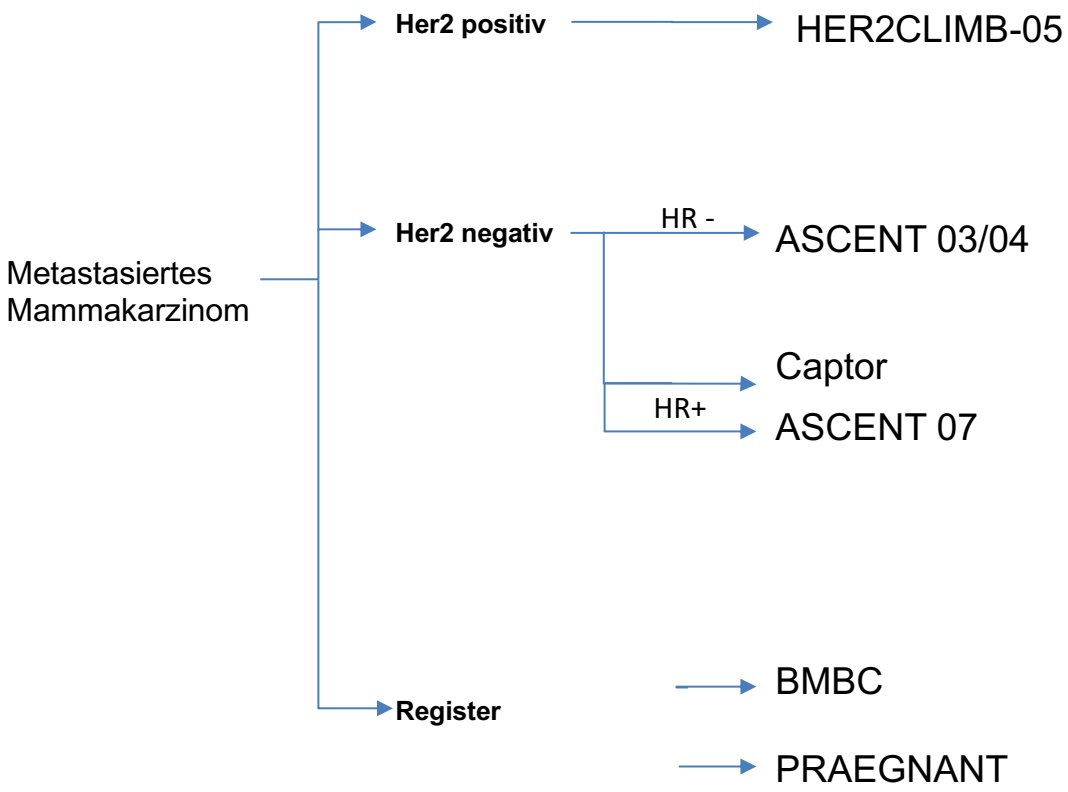
- Frauen mit pathogener Variante (Klasse 4/5) im *BRCA1*-Gen
- Alter ≥ 25 Jahre und ≤ 55 Jahre zum Zeitpunkt der Randomisation
- Kein klinischer Hinweis auf Ovarialkarzinom
- Negativer Schwangerschaftstest
- **Keine geplante Brustoperation**
- ECOG 0-1
- Schriftliches Einverständnis

Ausschlusskriterien

- **Bilaterale Mastektomie**
- Vorgeschichte mit Brust- oder Eierstockkrebs
- Vorgeschichte mit anderen Malignomen (außer Basaliom..)
- **Schwangerschaft oder Stillzeit**
- Keine Anwendung effizienter Verhütungsmethoden
- Klinisch relevante Hypokalziämie
- Oralchirurgische Implikationen
- Aktive Hepatitis B/C, HI-Virusinfektion

Weltweit erste medikamentöse Präventionsstudie gegen Brustkrebs für Frauen mit einer *BRCA1*-Mutation

Studienbaum
Metastasiertes Mamma-Ca



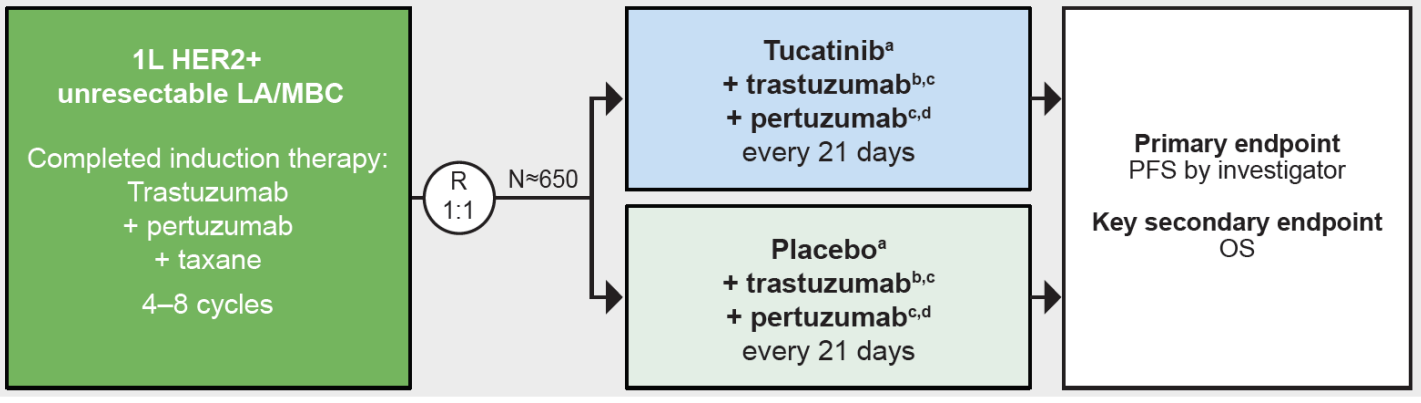
PHASE 3 STUDY OF TUCATINIB OR PLACEBO IN COMBINATION WITH TRASTUZUMAB AND PERTUZUMAB AS MAINTENANCE THERAPY FOR HER2+ METASTATIC BREAST CANCER (HER2CLIMB-05, TRIAL IN PROGRESS)

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 1L

- 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



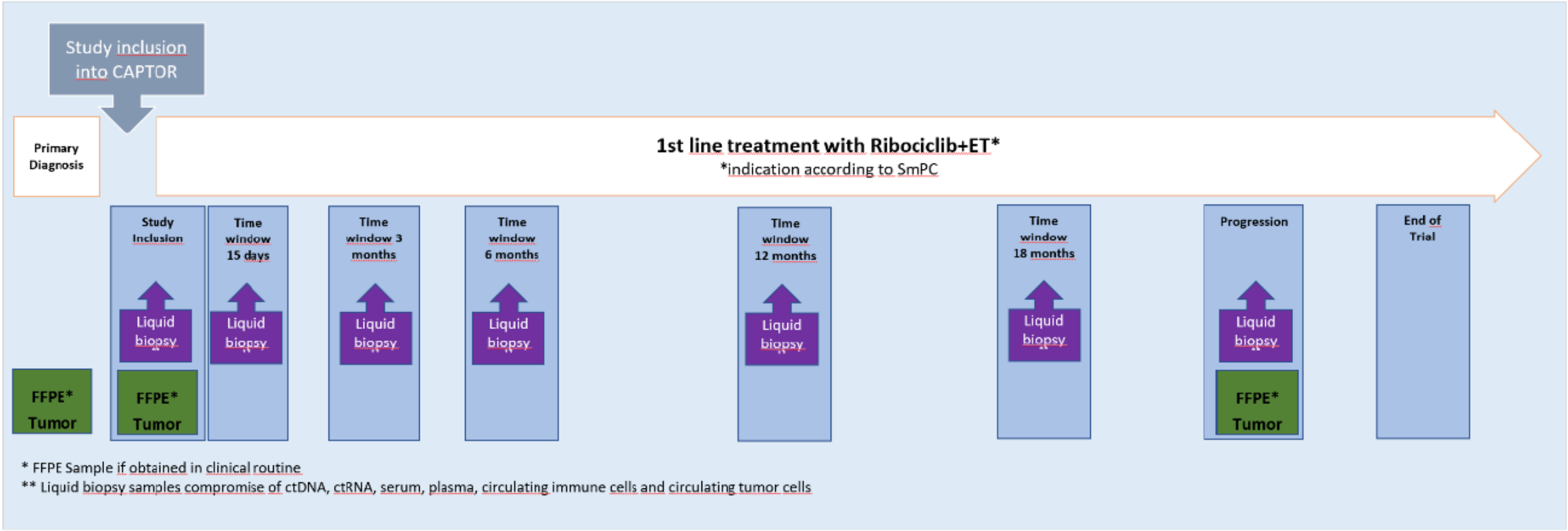
Randomization will be stratified by diagnosis (de novo vs recurrent MBC), hormone receptor status (positive vs negative), and presence or history of BM (yes vs no)
[a]Tucatinib/placebo 300 mg will be administered PO from Cycle 1 Day 1 onward, BID on each day of study treatment. [b]IV trastuzumab will 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.

- **Relevante Aspekte**
  - Screening cMRT vor Studieneinschluss
  - Asymptomatische HM erlaubt
  - Endokrine Therapie erlaubt

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



ASCENT-07

Phase 3, Randomized, Open-label Study of Sacituzumab Govitecan vs Treatment of Physician's Choice in Patients With HR+/HER2- Inoperable, Locally Advanced, or Metastatic Breast Cancer and Have Received Endocrine Therapy

GILEAD

Key Eligibility Criteria:

- ✓ HR+/HER2 negative, locally advanced and unresectable, or metastatic breast cancer.
- ✓ Eligible for first chemotherapy for advanced or metastatic breast cancer.
- ✓ No prior treatment with a topoisomerase I inhibitor.
- ✓ Measurable disease per RECIST v1.1.
- ✓ Patients must have one of the following:
  - Disease progression on ≥ 2 previous lines of ET with or without a targeted therapy in the metastatic setting.
  - Disease recurrence while on the first 24 months of starting adjuvant ET will be considered a line of therapy; these patients will only require 1 line of ET in the metastatic setting.
  - Disease progression within 6 months of starting first-line ET with a CDK 4/6 inhibitor or without a CDK 4/6 inhibitor (if ineligible or if unable to access a CDK 4/6 inhibitor*) in the metastatic setting.
  - Disease recurrence while on the first 24 months of starting adjuvant ET with CDK4/6i and if the patient is no longer a candidate for additional ET in the metastatic setting as determined by the Investigator.

N = 654

2:1 randomization

Sacituzumab govitecan
10 mg/kg IV
Days 1 and 8, every 21 days

Treatment of physician's choice (capecitabine, paclitaxel, nab-paclitaxel)

Stratification:

- Duration of prior CDK 4/6i in metastatic setting (none vs ≤ 12 mos vs > 12 mos)
- HER2 IHC (HER2 IHC 0 vs HER2 IHC-low ([IHC 1+; 2+/ISH-])
- Geographic region (US/CAN/UK/EU vs ROW)

Primary Endpoint

- PFS by BICR

Key Secondary Endpoints

- OS
- ORR by BICR
- Change from baseline in Physical Functioning and TTD of Global Health Status

Secondary Endpoints

- PFS by Investigator
- ORR by Investigator
- DOR
- Safety

BICR, blinded independent central review; CAN, Canada; CDK 4/6i, cyclin-dependent kinase 4/6 inhibitor; DOR, duration of response; ET, endocrine therapy; EU, European Union; HER2, human epidermal growth factor receptor 2; HR+, hormone receptor-positive; IHC, immunohistochemistry; ISH, *in situ* hybridization; IV, intravenous; mos, months; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; RECIST v1.1, Response Evaluation Criteria in Solid Tumors Version 1.1; ROW, rest of the world; TTD, time to deterioration; UK, United Kingdom; US, United States

Protocol Overview and Study Flow

Screening

28 days

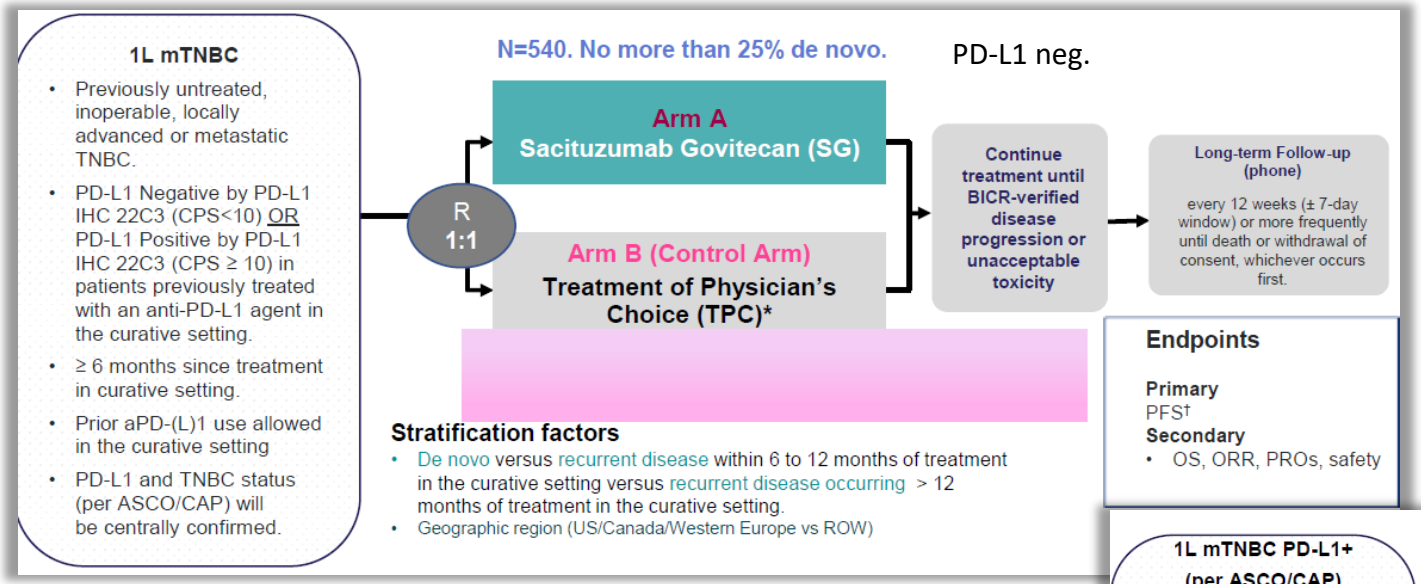
Treatment Period

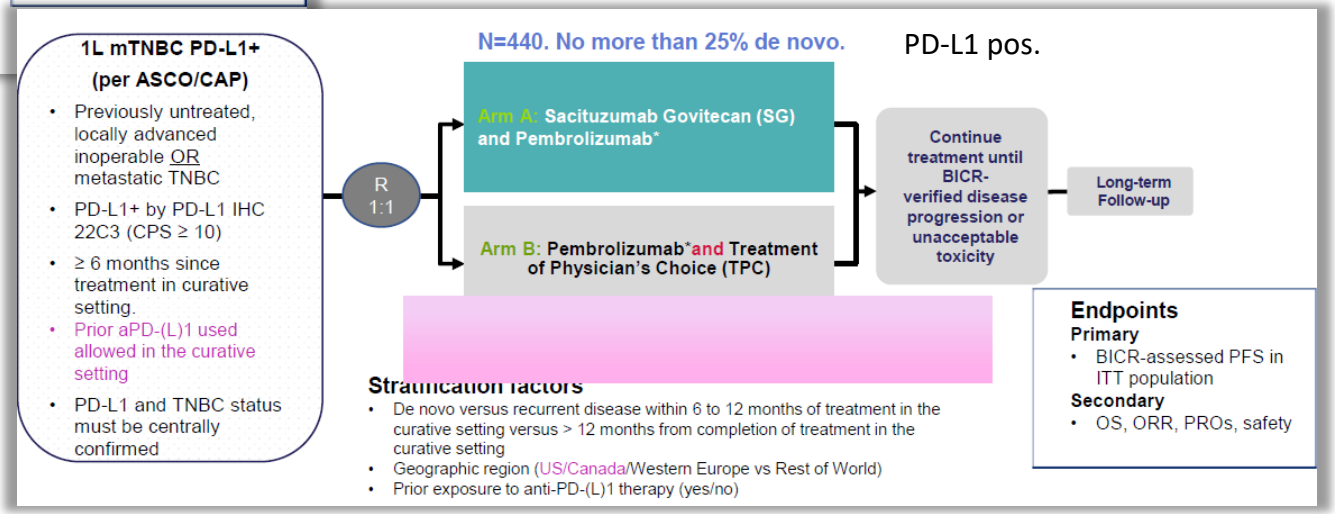
21-day cycles for SG and for capecitabine;
28-day cycles for paclitaxel and nab-paclitaxel.
Until PD as assessed by BICR, unacceptable toxicity, physician decision, consent withdrawal, or death.

Long-term follow-up

Starts 30 days after the end of treatment (EOT).
Follow-up visits every 12 weeks (± 2-week) or more frequently until death, withdrawal of consent, or end of study, whichever occurs first.

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





Studiendesign BMBC

STUDIEN POPULATION

- Histologisch gesichertes Mammakarzinom
- Hirnmetastase(n) mit Erstdiagnose nach 2000

→ **Einwilligung des Patienten*** → **REGISTRIERUNG** →

DATENSAMMLUNG

- Tumoreigenschaften des Primärtumors und der Metastase(n)
- Behandlungsdaten von Patienten
- Outcome

BIOMATERAL

- FFPE Gewebe Primarius und der Metastasen

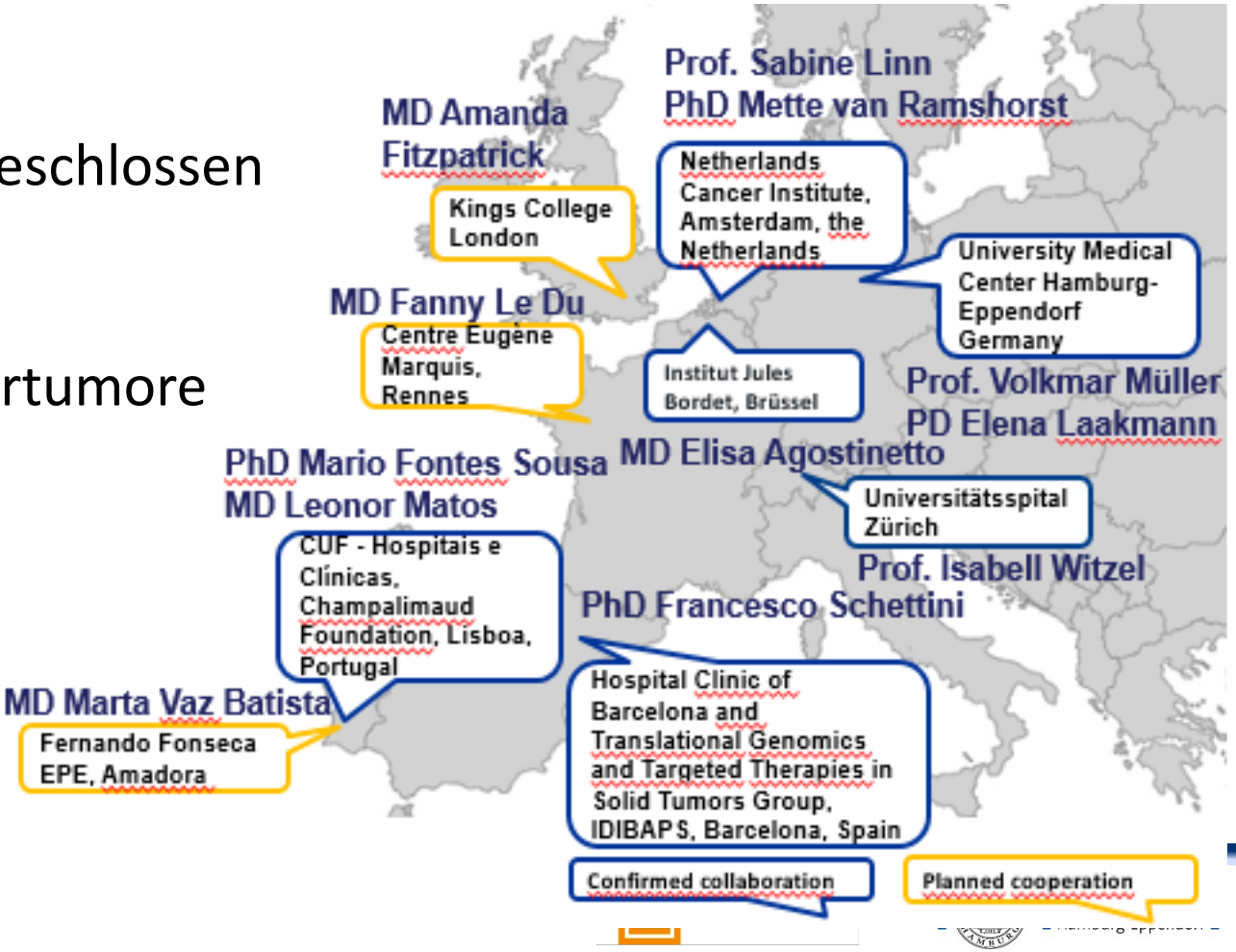
*bei prospektiver Datensammlung

- Daten von >4000 Patienten

UKE HAMBURG · TraFo · AGO-B BREAST STUDY GROUP · GBG GERMAN BREAST GROUP

BMBC Register

- Internationale Kooperationen
- Erste internationale Patientinnen eingeschlossen
- Datentransfer n=900 aus NCI
- Biobank: ca. 400 ZNS Met.+ 150 Primärtumore
- Finanzielle Förderung für 3 Jahre



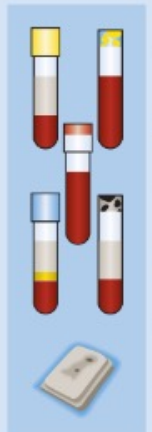
PRAEGNANT REGISTRY

PRAEGNANT MAMMAKARZINOM

Biomarker | Clinical factors | Molecular patterns | Genetic factors | Circulating tumor cells | Blood sample procedure

Biomarker Background Knowledge[1)]

There are different factors which influence the prognosis and possible treatment side-effects. Few of them could have a prognostic significance for patients with metastatic breast cancer, even if they are not yet used much in routine clinical practice. An additional aim is to take blood samples, as a kind of „liquid biopsies" after each therapy change, to track the possible change of the tumor characteristics.



Plasma	Protein analysis
Serum	Protein analysis
Germline DNA	Chromosomal aberrations, mutations, amplifications, deletions
Micro-RNA	Quantity, pattern, association with expression and protein analysis
Circulating tumor DNA	Chromosomal aberrations, mutations, amplifications, deletions
Leukocyte RNA	Leukocyte RNA expression
CTCs	Chromosomal aberrations, mutations, amplifications, deletions, RNA expression, protein analysis, cell cultures
FFPE	DNA analysis, RNA analysis, protein analysis

- >5000 Pat.
- Real-World-Daten
- Met. Mamma-Ca
- Klinische Daten, NW, PROs
- Molekulare Analytik, inkl. Keimbahntestung
- Analyse FFPE Gewebe

Deutsche Gesellschaft für Senologie

ARBEITSGEMEINSCHAFT GYNÄKOLOGISCHE ONKOLOGIE E.V.

DGHO DEUTSCHE GESELLSCHAFT FÜR HÄMATOLOGIE UND ONKOLOGIE

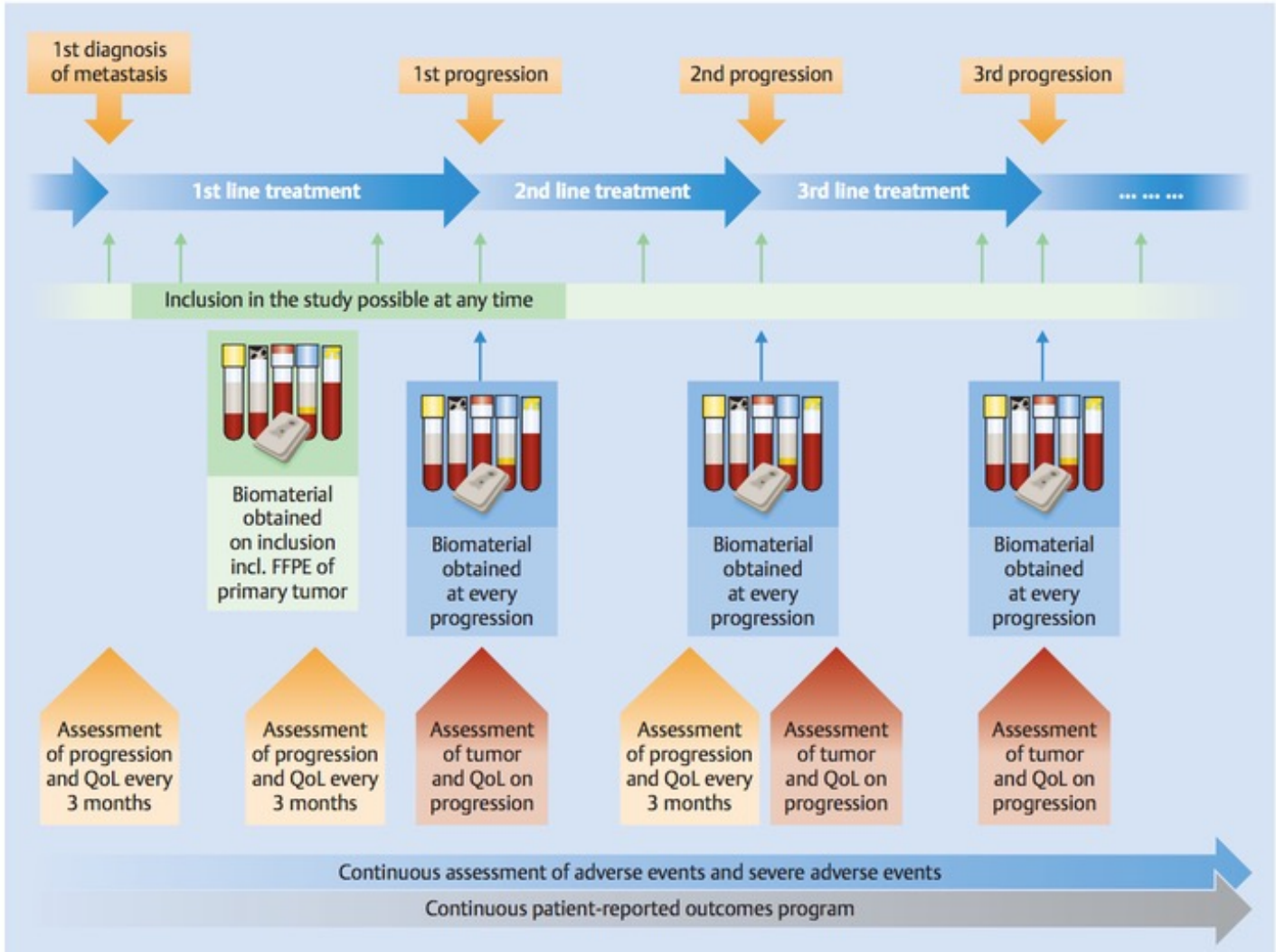
Hubertus Wald Tumorzentrum Universitäres Cancer Center Hamburg

Universitätsklinikum Hamburg-Eppendorf

PRAEGNANT REGISTRY

PRAEGNANT
MAMMAKARZINOM

Blood sample of each patient will be taken at the beginning of the study and after each change of therapy.

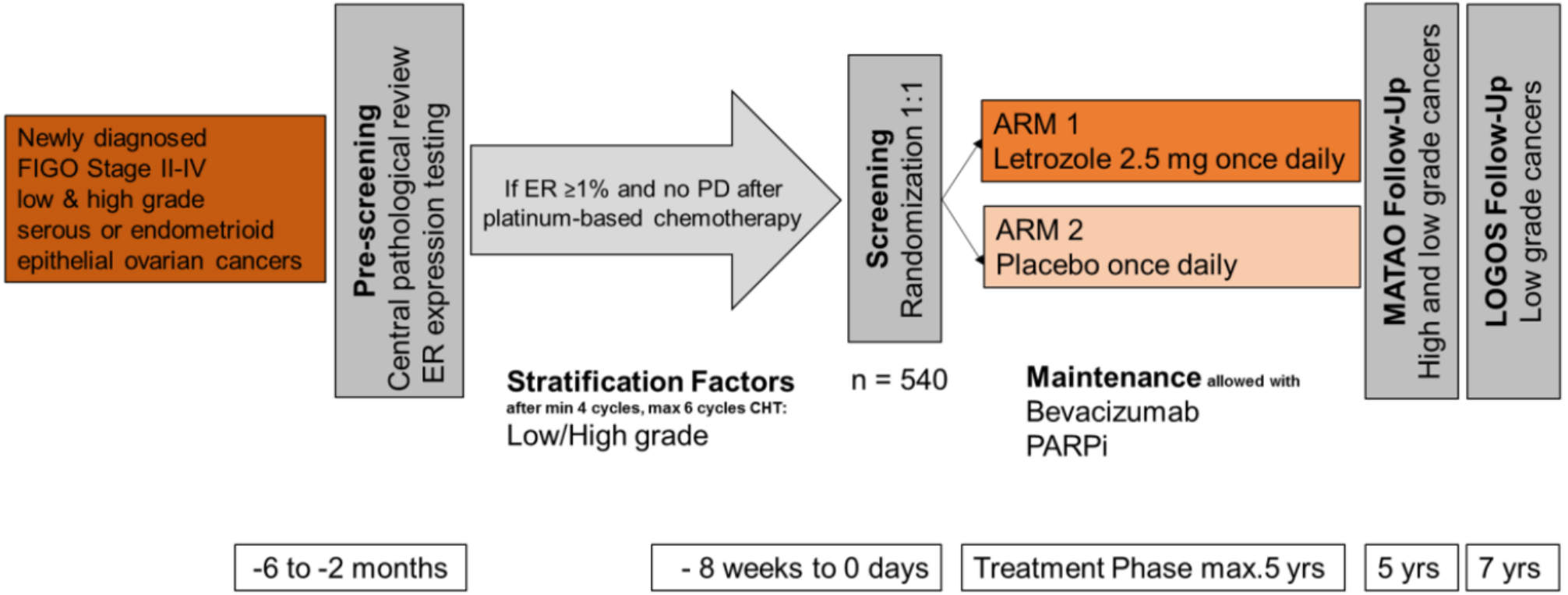


Studienübersicht gynäkologische Karzinome

1. **Ovarialkarzinom**
   - Erstdiagnose
     - Systemtherapie: **AGO-OVAR 26 / MATAO, AGO-OVAR 28**
     - Bewegungs-und Ernährungstintervention: **BENITA**
     - Real-world clinical data / PRO**: SCOUT-1 (NOGGO ov54)**
   - Rezidiv
     - TPI > 3 Monate: **AGO-OVAR 2.34 / MIROVA**
     - platin-resistent**: MITO-33 NItCHE trial**
2. **Zervixkarzinom**
   - Systemtherapie fortgeschrittenes, metastasiertes CxCA: **SENTICOL III** (Rekrutierung beendet)
   - Qualitätssicherung met. CxCA**: QS-CXmet 2018-2022**
3. **Vulvakarzinom**
   - Systemtherapie fortgeschrittenes, metastasiertes VSCC**: AGO-VULVA-1 / PIERCE**
4. **Endometriumkarzinom**
   - Operative Therapie: **ECLAT**

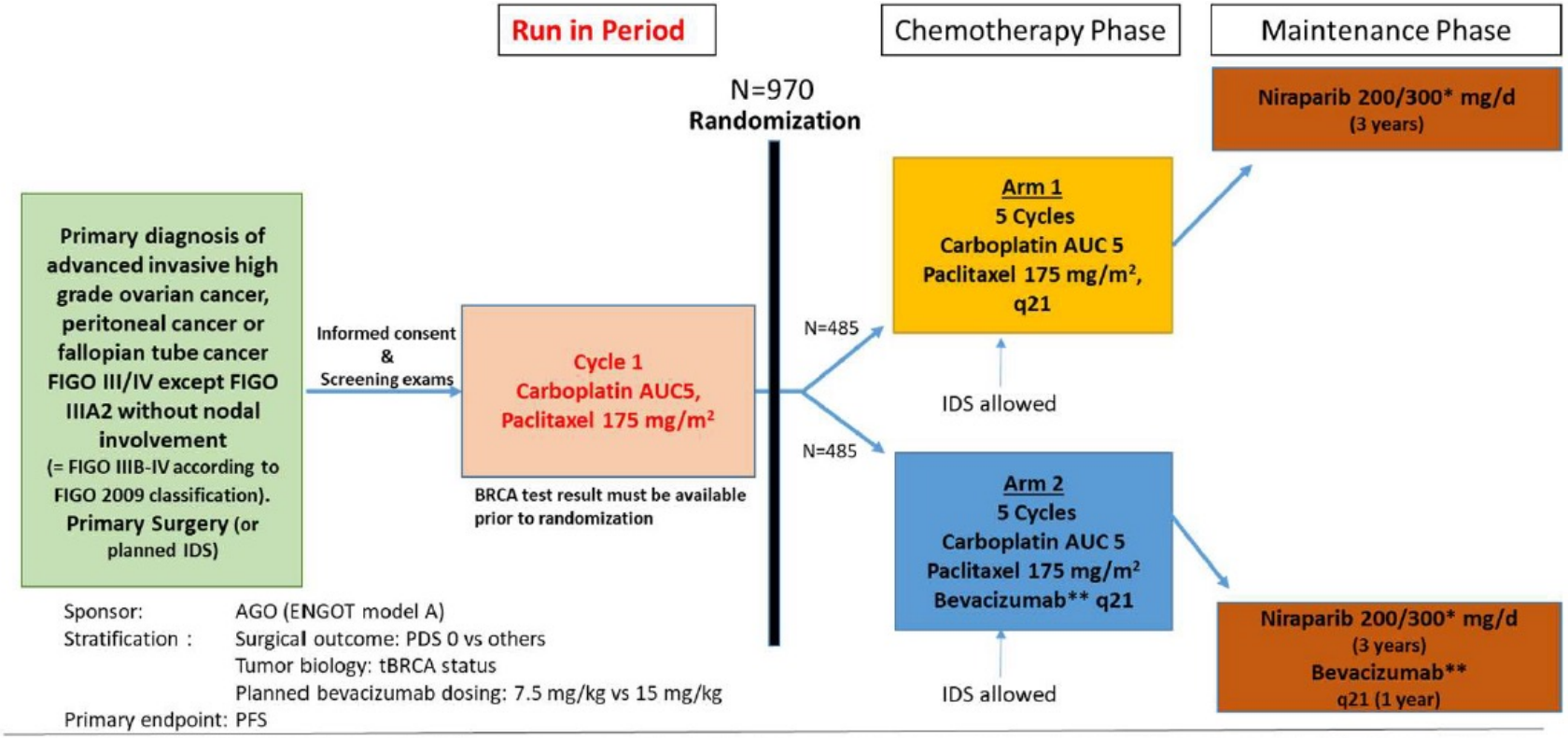
Ovarialkarzinom

Wirksamkeit einer Erhaltungstherapie mit Aromatasehemmer (Letrozol) für Patientinnen mit epithelialem Ovarialkarzinom: eine randomisierte doppelblinde Placebo-kontrollierte multizentrische Phase III Studie



Inclusion	Exclusion
• **Patients must be ≥ 18 years of age** • **Willing and able to attend the visits, to understand all study-related procedures** • **Primary, newly diagnosed FIGO Stage II to IV and histologically confirmed low or high grade serous or endometrioid epithelial ovarian/fallopian tube/peritoneal cancer** • **(Interval-) debulking performed** • **ECOG-Performance Status 0-2** • **Signed informed consents (ICF-1**; ICF-2) • **Paraffin-embedded tissue or paraffin-embedded cell block (from ascites) available** • Positivity (≥ 1%) for ER expression (only determined by Histopathology Core Facility of MATAO trial) • At least 4 cycles of platinum-based chemotherapy (neoadjuvant allowed) • Negative serum pregnancy test in women of childbearing potential who will get/have gotten a surgical resection or radiation sterilization, prior to the intervention in the therapeutical maintenance setting.	• Progressive disease at the end of adjuvant treatment • **Women of childbearing potential (not having had nor will getting a surgical resection, prior to the intervention in the therapeutically maintenance setting)** • **Pregnant or lactating women** • **Any other malignancy within the last 5 years which has impact on the prognosis of the patient** • < 4 cycles of chemotherapy in total • **Contraindications to endocrine therapy** • **Inability or unwillingness to swallow tablets** • **Patients with a known intolerance to galactose, lactase deficiency and glucose-galactose mal-absorption**

Multizentrische, randomisierte Phase III Studie: Niraparib vs. Niraparib + Bevacizumab bei Patientinnen mit fortgeschrittenem Ovarialkarzinom nach Carboplatin-Taxan haltiger Chemotherapie



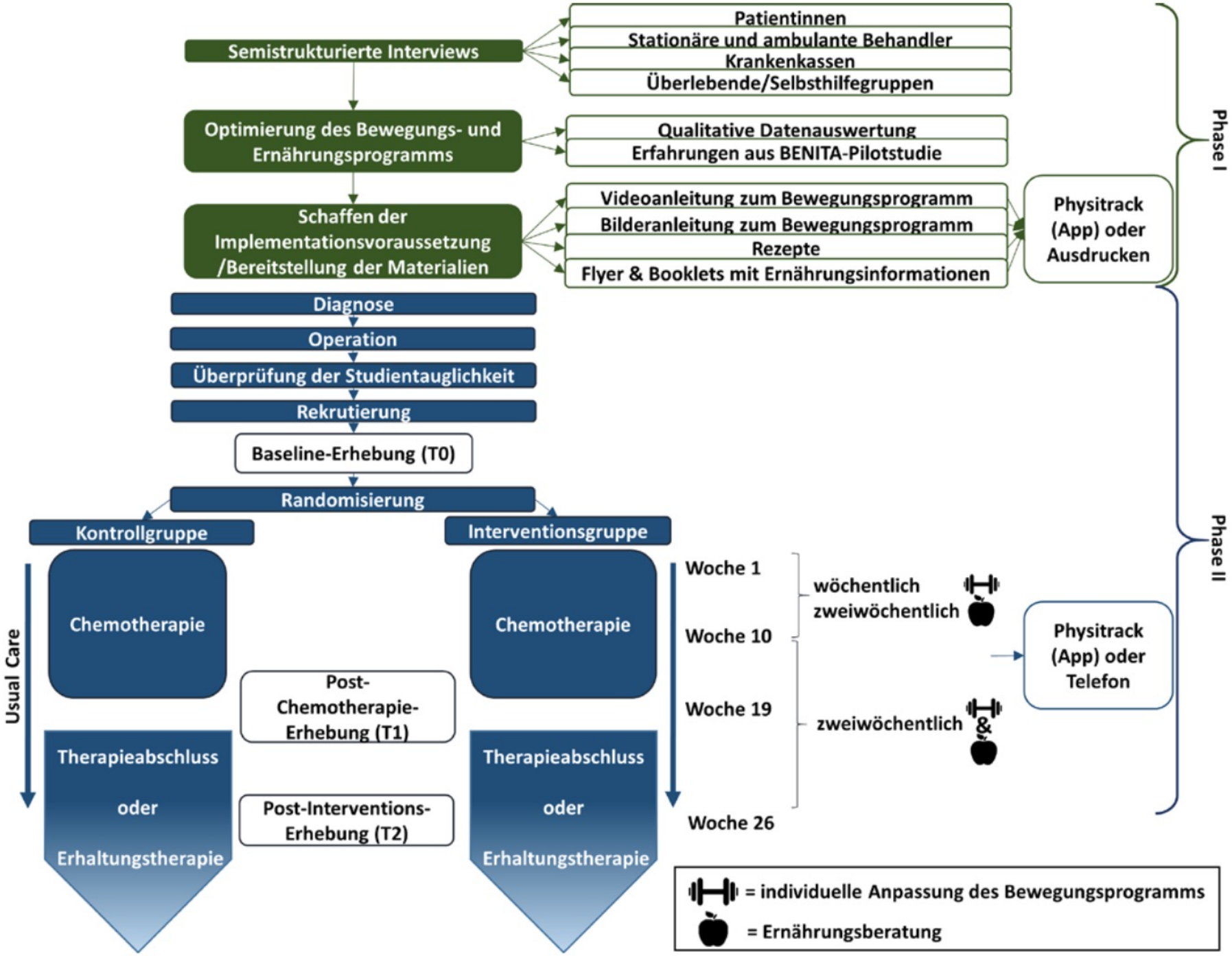
* The recommended starting dose of niraparib is 200 mg, taken once daily. For those patients who weigh ≥ 77 kg and have baseline platelet count ≥ 150,000/µL the recommended starting dose of niraparib is 300 mg, taken once daily.

** 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

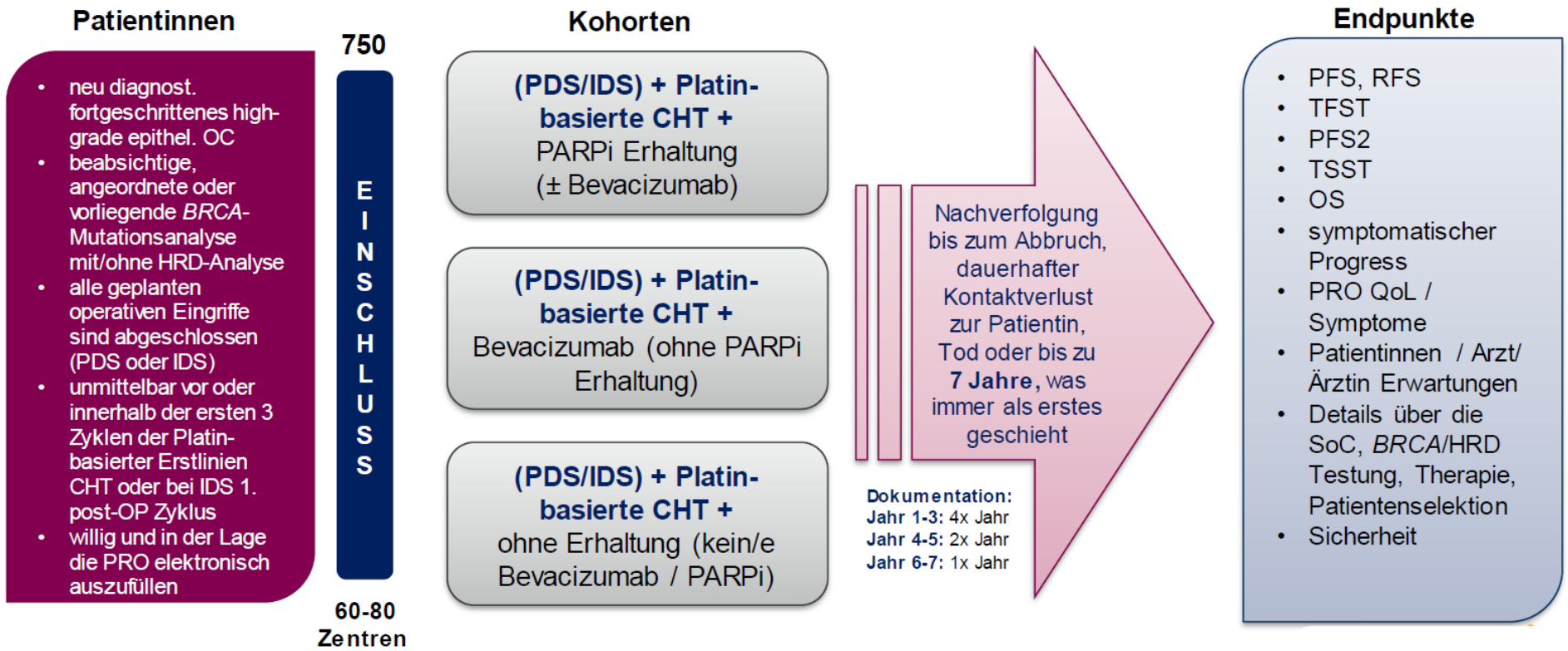
Stratification:

- 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.

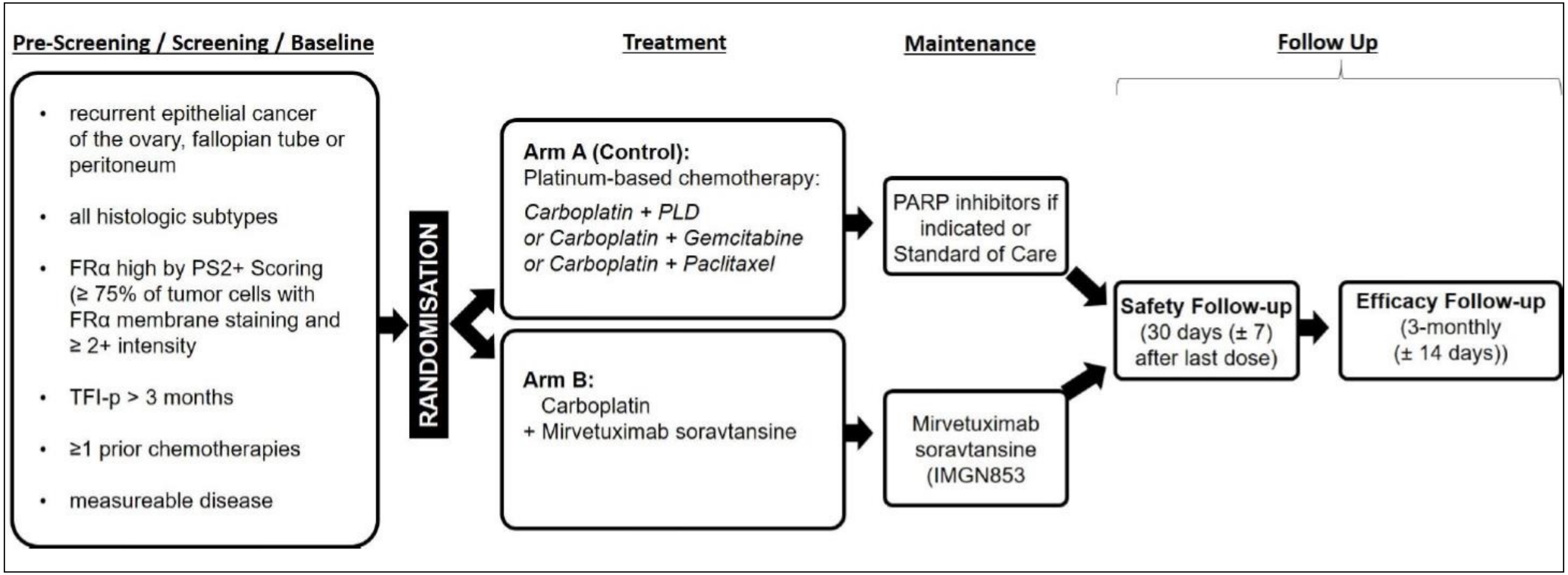

Semistrukturierte Interviews
Patientinnen
Stationäre und ambulante Behandler
Krankenkassen
Überlebende/Selbsthilfegruppen
Optimierung des Bewegungs- und Ernährungsprogramms
Qualitative Datenauswertung
Erfahrungen aus BENITA-Pilotstudie
Schaffen der Implementationsvoraussetzung /Bereitstellung der Materialien
Videoanleitung zum Bewegungsprogramm
Bilderanleitung zum Bewegungsprogramm
Rezepte
Flyer & Booklets mit Ernährungsinformationen
Physitrack (App) oder Ausdrucken
Phase I
Diagnose
Operation
Überprüfung der Studientauglichkeit
Rekrutierung
Baseline-Erhebung (T0)
Randomisierung
Kontrollgruppe
Interventionsgruppe
Usual Care
Chemotherapie
Chemotherapie
Post-Chemotherapie-Erhebung (T1)
Therapieabschluss oder Erhaltungstherapie
Therapieabschluss oder Erhaltungstherapie
Post-Interventions-Erhebung (T2)
Woche 1
wöchentlich
zweiwöchentlich
Woche 10
Woche 19
zweiwöchentlich
Woche 26
Physitrack (App) oder Telefon
Phase II
= individuelle Anpassung des Bewegungsprogramms
= Ernährungsberatung

Prospective non-interventional Study to Collect real-world clinical and patient-reported OUTcome data in ovarian cancer patients eligible for first-line platinum-based chemotherapy and intended for BRCA/HRD testing

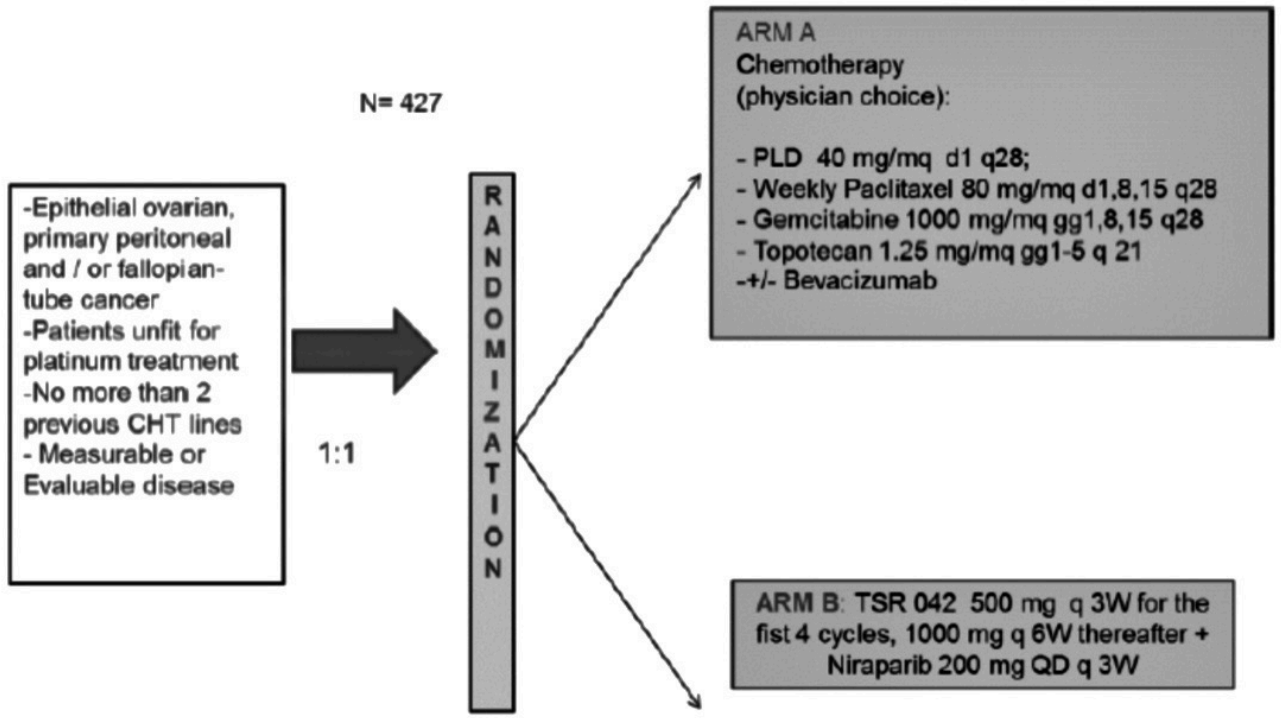
Studiendesign



Phase-II-Studie zum Einsatz von Mirvetuximab Soravtansin bei Patientinnen mit rezidivierendem Ovarialkarzinom und hoher Folatrezeptor-alpha (FRα)-Expression



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)

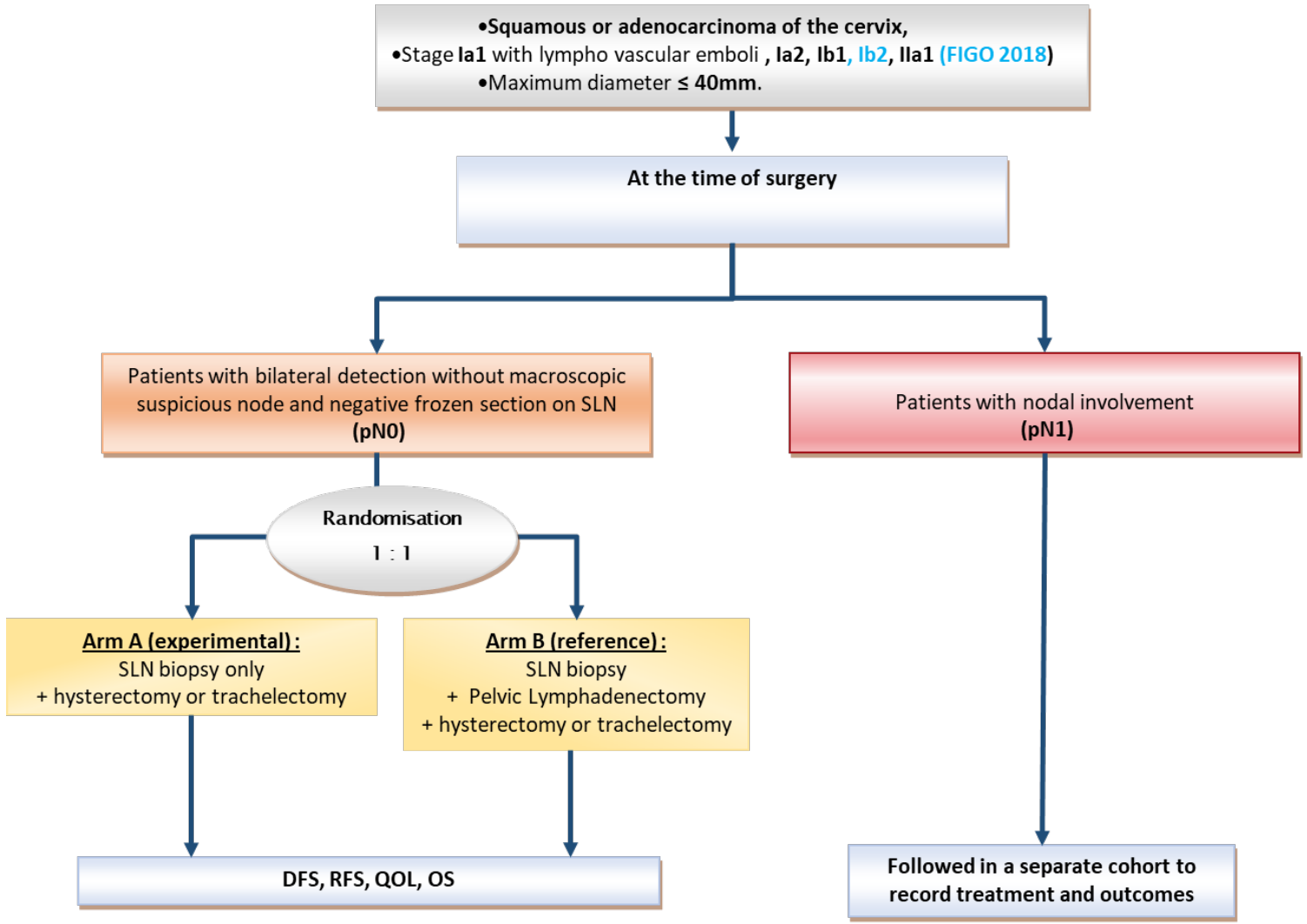
1.Participants have received >2 previous CHT lines (previous treatment with parp inhibitors and/or anti check point inhibitors is allowed providing that at least 6 months from last treatment are intercurred)
2. Participant has had radiation therapy encompassing >20% of the bone marrow within 2 weeks; 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

Zervixkarzinom

SENTICOL III

Internationale Validierungsstudie zur Sentinel-Biopsie beim frühen Zervixkarzinom – prospektive, multizentrische, randomisierte Phase III Studie

REKRUTIERUNG BEENDET



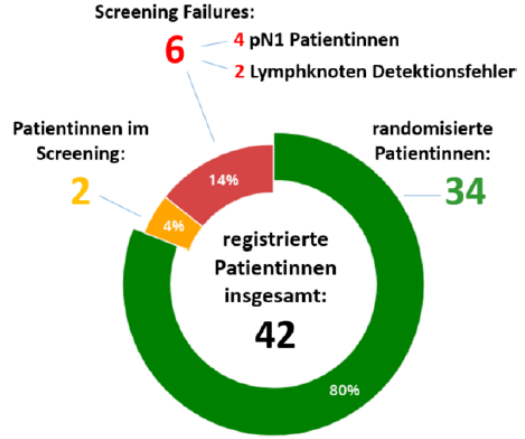


Abbildung 1: Rekrutierung in Deutschland (Stand 25.09.2023)

	pN0 / pN1	Geplant Juni 2024	Aktiv (Monate)
Hannover	9 / 1	18	14
Essen	9 / 1	20	12
Düsseldorf FNK	5	14	12
Hamburg UKE	4	16	7
Lübeck	3	8	8
Wolfsburg	1 / 1	24	12
Rostock	1	20	11
Düsseldorf HHU	1	16	3
Dresden	1 / 0	14	7
Münster	0 / 1	4	7
Fürth	0	4	1
Kassel	0	4	3
Karlsruhe	0	6	12
Berlin Vivantes	0	14	5
Jena	0	16	7

Qualitätssicherung metastasiertes Zervixkarzinom – Evaluation von Patientinnen Charakteristika und therapeutischen Behandlungsstrategien - eine multizentrische retrospektive Längsschnittstudie

- N= 300, multizentrische retrospektive Längsschnittstudie
- Zielpopulation: Pat., die zwischen 2018 - 2022 in D mit einem metastasierten CxCA FIGO IVB oder Rezidiv diagnostiziert wurden
- Endpunkte: Hauptziel der Studie ist die Versorgungsforschung und Qualitätssicherung. Die Therapiestrategien und deren Ergebnisse im klinischen Alltag sollen entsprechend der Ausgangscharakteristika der Pat. analysiert werden.
  - 1. Erstlinientherapie für metastasiertes oder fortgeschrittenes Zervixkarzinom
  - 2. Progressionsfreies- und Gesamtüberleben
  - 3. Folgetherapien
- Intervention: Beschreibung und Dokumentation zu Patientencharakteristika, Behandlungsmodalitäten und klinischem Outcome
- Eingeschlossene Pat: N= 38 Pat, UKE: 27 Pat, KHJ 11 Pat.

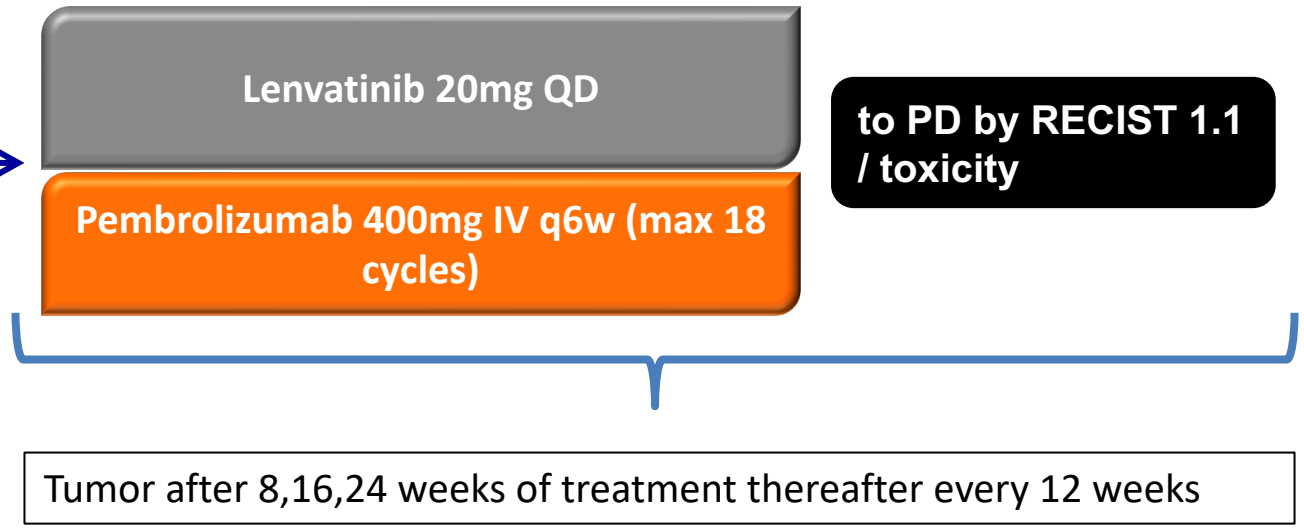
Vulvakarzinom

Pembrolizumab in combination with lenvatinib in patients with recurrent, persistent, metastatic or locally advanced vulvar cancer not amenable to curative surgery or radiotherapy - A multicenter, phase II study

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

N=42

- 15 Zentren in Deutschland geplant
- Rekrutierungsdauer 36 Monate
- Dauer der Studie insgesamt: 48 - 60 Monate



Primary endpoint: investigator-assessed ORR within 24weeks evaluated by RECIST 1.1
Secondary endpoints: OS, PFS, DOR, DCR, TSST, frequency of SAEs, frequency of dose reductions, delays/interruption and health-related QoL(EORTC QLQ-C30 und EORTC QLQ-CU34)

Endometriumkarzinom

Endometrial Cancer Lymphadenectomy Trial (ECLAT)

Pelvic and Para-aortic Lymphadenectomy in Patients with Stage I or II Endometrial Cancer with High Risk of Recurrence

ECLAT

PRIMARY SURGERY

Patients with histologically confirmed endometrial cancer and high risk of recurrence

clinical stage T1b - T2 (all histological types and gradings) orT1a (type 1-EC, G3; type 2-EC)

↓

Baseline Visit (max. 3 weeks prior to surgery)

↓

Randomization *during primary surgery* ***(if no macroscopically suspect lymph nodes)***

Arm A	Arm B
primary surgery total hysterectomy, bilateral salpingo-oophorectomy, omentectomy (type 2-EC) **no lymphadenectomy (LNE)**	**primary surgery** total hysterectomy, bilateral salpingo-oophorectomy, omentectomy (type 2-EC) **LNE** (systematic pelvic and para-aortic lymphadenectomy up to the renal vessels)

ECLAT

SECONDARY SURGERY

Patients with histologically confirmed endometrial cancer and high risk of recurrence

clinical stage pT1b - pT2 (all histological types and gradings) or pT1a (type 1-EC, G3, type 2-EC) ***found after hysterectomy*** for supposed low risk EC and no LNE performed and no suspect lymph nodes

↓

Baseline Visit (max. 3 weeks prior to secondary surgery, secondary surgery max. 8 weeks after first surgery): ALL inclusion/exclusion criteria need to be verified based on standard documents - otherwise Randomization is not allowed. Randomization max. 2 weeks before secondary surgery

↓

a: Randomization *before secondary surgery* (all surgical procedures already done, no LNE so far)

b: Randomization *before secondary surgery* (not all surgical procedures already done e.g. omentectomy, no LNE so far)

Arm A	Arm B
a : no LNE = no further surgery	**a: LNE** (systematic pelvic and paraaortic LNE up to the renal vessels)
b: secondary surgery to perform so far missing standard procedures **no LNE**	**b: secondary surgery to perform so far missing standard procedures** **LNE**

ECLAT

PRIMARY AND SECONDARY SURGERY