Mapping Clinical Trial Eligibility Criteria to EMR Data (Breast Cancer Trials)

1. Demographic Criteria

Term	Structured (FHIR)	Coding System	Unstructured Sources
Sex	Patient.gender	N/A	Admission notes, discharge summaries
Age	Patient.birthDate	N/A	Discharge summaries, intake forms
Menopausal Status	Observation	LOINC 45820-6 (e.g., FSH level)	Clinical notes, pathology reports
Reproductive Status	Observation, QuestionnaireResponse	LOINC 19080-1 (Pregnancy status)	Consent forms, clinical notes
Caregiver Consent	Not standard	N/A	Consent notes, trial intake summary

Rules:

- Sex: Must be female unless trial specifies inclusion of males.
- Age: Must be ≥18, sometimes ≤70 (check protocol).
- Menopausal status: Required for hormone therapy trials; inferred if not documented.
- Reproductive status: Women of childbearing potential must use contraception and have negative pregnancy test.
- Caregiver consent: Only needed if trial specifies or patient lacks decisional capacity.

2. Clinical Criteria

Term	Structured (FHIR)	Coding System	Unstructured Sources
ECOG Performance Status	Observation	LOINC 89243-0	Oncologist notes, clinic flowsheets
Comorbidities	Condition	ICD-10, SNOMED	Problem list, discharge summaries
Cardiac Function (LVEF)	Observation, DiagnosticReport	LOINC 33878-0	Echo/MUGA reports
Liver Function	Observation	LOINC 1742-6 (AST), 1920-8 (ALT), 1975-2 (bilirubin)	Lab summaries, scan follow-ups
Renal Function	Observation	LOINC 2160-0 (Creatinine), 62238-1 (eGFR)	Lab panels, nephrology notes

HIV/Hepatitis Status	Observation, Condition	LOINC 25835-0 (HIV), SNOMED for diagnoses	Infectious disease notes

Rules:

- ECOG must be 0–1, sometimes 2 accepted.
- No significant uncontrolled comorbidities (e.g., Class III/IV heart failure).
- LVEF must be ≥50% (HER2 trials).
- Liver enzymes (AST/ALT) must be ≤2.5× ULN (≤5× ULN with liver mets).
- Creatinine clearance ≥50–60 mL/min.
- No uncontrolled infections (HIV with detectable viral load, active hepatitis).

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3. Diagnosis Criteria

Term	Structured (FHIR)	Coding System	Unstructured Sources
Breast Cancer Diagnosis	Condition	ICD-10 C50.*, SNOMED	Pathology report, problem list
Stage	Condition.stage or Observation	AJCC, TNM	Oncology summaries, imaging reports

Rules:

- Must have histologically confirmed breast cancer.
- Stage must match trial focus (e.g., non-metastatic for adjuvant trials, Stage IV for metastatic trials).

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4. Pathology/Biomarker Criteria

Term	Structured (FHIR)	Coding System	Unstructured Sources
ER/PR/HER2	Observation	LOINC 85337-4, 85339-0, 85340-8	Pathology reports
BRCA Mutation	Observation, FamilyMemberHistory	LOINC 81247-9, SNOMED for mutation presence	Genetic reports, clinical notes
PIK3CA	Observation	Custom/local codes or sequencing panel IDs	Molecular reports, NGS panel PDFs
PD-L1	Observation	LOINC 81288-3	Pathology addenda
Oncotype DX / Recurrence Score	Observation	LOINC 77353-1	External lab reports (PDF)
Node Status	Observation, Condition	SNOMED or TNM coding	Pathology report (synoptic)

Rules:

- ER/PR ≥1% = hormone receptor positive; HER2 3+ or FISH+ = HER2 positive.
- Triple-negative = ER/PR <1%, HER2 0–1+ (or 2+ FISH−).
- Must match trial subtype (e.g., HER2+, HR+, TNBC).
- BRCA mutation required for PARP inhibitor trials.
- PIK3CA mutation required for PI3K inhibitor trials.
- Oncotype score used for risk stratification in some adjuvant trials.
- Nodal status (e.g., ≥4 positive nodes) used for eligibility in early-stage trials.

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5. Treatment History Criteria

Term	Structured (FHIR)	Coding System	Unstructured Sources
Chemotherapy Regimens	MedicationAdministration, Procedure	RxNorm	Oncologist notes, chemo flowsheets
Surgery	Procedure	SNOMED, CPT	Operative reports
Radiation	Procedure	SNOMED, CPT	Radiation oncology summaries
Treatment Lines	CarePlan (summary), Encounter sequence	N/A	Oncology treatment summaries

Rules:

- Adjuvant trials: must have completed surgery ± chemo/radiation ≥4 weeks prior.
- Metastatic trials: specify allowed prior lines (e.g., 0 for 1st-line, 1 for 2nd-line).
- Must not have had prior exposure to study drug class (e.g., CDK4/6 inhibitors).
- No major surgery or radiation within past 2–3 weeks unless allowed.

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6. Imaging Criteria

Term	Structured (FHIR)	Coding System	Unstructured Sources
Brain Metastases	Condition, DiagnosticReport	SNOMED	Radiology reports (MRI)
Measurable Disease	Observation	N/A	Radiology reports, tumor measurement notes
Staging Scans	DiagnosticReport	CPT codes for imaging	Radiology summaries, oncology staging notes
LVEF (again)	Observation	LOINC 33878-0	Echo reports

Rules:

- Brain metastases: Allowed only if treated and stable ≥4 weeks, off steroids.
- Measurable disease per RECIST 1.1 required unless otherwise stated.
- Early-stage: must show no metastasis on baseline imaging.

- LVEF must meet threshold (≥50%) confirmed via imaging.

7. Laboratory Criteria

Term	Structured (FHIR)	Coding System	Unstructured Sources
Hematology Panel	Observation	LOINC (e.g., 26464-8 CBC panel)	Lab reports
Liver Panel	Observation	LOINC (e.g., 24323-8)	Lab reports
Renal Panel	Observation	LOINC (e.g., 2160-0 creatinine)	Lab reports
Glucose & Lipids	Observation	LOINC (e.g., 4548-4 glucose, 2093-3 cholesterol)	Lab summaries
Calcium	Observation	LOINC 17861-6	Lab reports
Pregnancy Test	Observation	LOINC 19080-1	Lab results, intake forms
Viral Load (Hep B/C)	Observation	LOINC 29610-5 (HBV), 20416-4 (HCV RNA)	ID clinic notes, lab PDF

Rules:

- ANC ≥ 1500/μL, Platelets ≥ 100,000, Hb ≥ 9–10 g/dL.
- Liver enzymes and bilirubin within defined limits (e.g., ≤2.5× ULN unless liver mets).
- CrCl ≥ 50–60 mL/min.
- Pregnancy test must be negative at baseline.
- HbA1c < 8% for drugs affecting glucose (e.g., AKT inhibitors).
- Lipids within normal or treated if drug impacts lipids.
- Normal calcium for bone-affecting drugs.
- Viral load for Hep B/C must be undetectable if infection present.

A Term-to-Representation Mapping Table

Category	Term	FHIR Resource	Coding System
Demographic	Sex	Patient.gender	N/A
Demographic	Age	Patient.birthDate	N/A
Demographic	Menopausal Status	Observation	LOINC 45820-6
Clinical	ECOG Status	Observation	LOINC 89243-0
Clinical	Cardiac Function (LVEF)	Observation	LOINC 33878-0
Clinical	Liver Function (AST/ALT)	Observation	LOINC 1742-6, 1920-8
Clinical	Renal Function	Observation	LOINC 2160-0, 62238-1

Diagnosis	Breast Cancer Dx	Condition	ICD-10 C50.*, SNOMED
Diagnosis	Stage	Condition.stage	TNM
Biomarker	ER/PR/HER2	Observation	LOINC 85337-4, 85339-0, 85340-8
Biomarker	BRCA Mutation	Observation	LOINC 81247-9
Biomarker	PD-L1	Observation	LOINC 81288-3
Treatment	Chemotherapy	MedicationAdministration	RxNorm
Treatment	Surgery	Procedure	SNOMED, CPT
Imaging	Brain Metastases	Condition	SNOMED
Imaging	Measurable Disease	Observation	N/A
Lab	CBC Panel	Observation	LOINC 26464-8
Lab	Pregnancy Test	Observation	LOINC 19080-1

Note: FHIR mappings may vary slightly across institutions depending on implementation. Validation often involves both automated and manual review of EMR data and supporting documents.