Metastatic breast cancer

HR-positive - HER2-low - PIK3CA-mutated - liver metastases

MUSTER-01 - 57 years - female - ECOG 1

SYNTHETIC SAMPLE CASE - for platform demonstration only. No real person, no documented treatment success and no individual treatment instruction.

Executive Summary

This sample report demonstrates how Medical Evidence AI converts clinical baseline information, pathology, molecular biomarkers, organ function and supportive immune/tumour-dynamics data into a structured evidence discussion. Validated treatment-relevant findings are explicitly separated from exploratory additional findings.

Core clinical question

Which diagnostic information changes the treatment discussion, which evidence-based options fit this disease setting, and which open issues should be clarified before the next treatment decision?

Clinical Review Required

Medical Evidence AI provides structured evidence synthesis as a basis for professional discussion. This sample report is not a diagnosis, prescription or individual treatment instruction. Treatment decisions remain with the qualified treating team/tumour board. Current approvals, guidelines and trial availability must be checked for every live case.

1. Clinical course & structured diagnostics

Metastatic breast cancer

Clinical course

• 02/2025: invasive breast carcinoma NST, grade 3; initially M0.

• 03/2025: breast-conserving surgery and sentinel-node biopsy followed by adjuvant chemotherapy and radiotherapy.

• Subsequent endocrine therapy; exact agent, duration and possible prior CDK4/6 exposure must be confirmed.

• 08/2026: three new liver lesions; biopsy confirms metastatic breast carcinoma.

Diagnostics & biomarkers

• Metastatic biopsy: ER 90%, PR 20%, HER2 IHC 1+ (HER2-low), Ki-67 45%.

• Activating PIK3CA alteration; ESR1 and AKT1/PTEN status should be completed where clinically relevant.

• Germline BRCA1/2/PALB2 testing initiated; result pending.

• Example laboratory context: Hb 11.8 g/dL, CRP 8.4 mg/L, creatinine 0.91 mg/dL, bilirubin 0.9 mg/dL, AST 48 U/L, ALT 51 U/L.

• Supportive TBNK profile may be documented with laboratory reference ranges but is not a stand-alone treatment indication.

Why these diagnostics matter

The purpose is not to collect the maximum number of laboratory values. The report separates findings that can select an established treatment, findings that affect safety or dosing, and measurements that provide supportive or exploratory longitudinal context. This distinction reduces the risk that immune-cell counts or CTC measurements are treated as stand-alone treatment indications.

2. Evidence Interpretation

• HR-positive disease makes endocrine sensitivity and prior endocrine exposure central to sequencing.

• PIK3CA is a clinically relevant biomarker; usability depends on treatment line, previous therapy and regional approval.

• HER2 IHC 1+ supports a HER2-low evidence discussion in an appropriate treatment line.

• Current metastatic biopsy is more relevant than an old primary-tumour receptor result if discordance exists.

Options for professional discussion

• Endocrine/targeted combinations according to prior CDK4/6 exposure, resistance profile and current approvals.

• PI3K/AKT-pathway targeted treatment where biomarker, line of therapy and safety profile match.

• HER2-low antibody-drug conjugate in an appropriate later-line setting after confirmation of eligibility.

• Chemotherapy when endocrine-based treatment is no longer appropriate or rapid disease control is required.

Interpretation limits

Temporal association between treatment, immune status, CTC trajectory and imaging does not establish causality. In a live report, assay method, reference ranges, treatment timing, imaging and clinical course must be assessed together. No option is automatically ranked as the correct treatment.

3. Evidence Matches - study comparison

Medical Evidence AI does not present study titles alone. The relevant elements are population, intervention, clinically relevant outcome, match to the case and limitations of transferability.

INAVO120 / PIK3CA-directed evidence

Population / evidence: PIK3CA-mutated HR-positive/HER2-negative advanced breast cancer in a defined endocrine-resistant setting.

Match to this sample case: PIK3CA mutation makes the evidence biologically relevant; exact prior endocrine/CDK4/6 history must match.

Limitation: Do not transfer without checking line of therapy, approval and safety criteria.

CAPItello-291

Population / evidence: HR-positive/HER2-negative advanced breast cancer after endocrine therapy; AKT-pathway biomarker subgroup relevant.

Match to this sample case: Potentially relevant if AKT1/PTEN/PIK3CA context and previous therapy fit.

Limitation: Biomarker definition and treatment sequence must be verified.

DESTINY-Breast06

Population / evidence: HR-positive metastatic HER2-low/ultralow disease after endocrine-based therapy.

Match to this sample case: HER2 IHC 1+ fits the HER2-low concept if quality-assured and line of therapy is appropriate.

Limitation: Pulmonary risk, previous therapy and current regional label require review.

4. Applicability & evidence gaps

Evidence gaps

• Exact endocrine and CDK4/6 treatment history.

• Current ESR1 and AKT1/PTEN status where relevant to sequencing.

• Final germline BRCA1/2/PALB2 result.

• Current extent of liver disease, pace of progression and organ-function trend.

Exploratory / immunological context

Immune-cell enumeration may describe the measured compartment but does not establish anti-tumour immune function or indicate dendritic-cell therapy. This sample intentionally demonstrates that immunological treatments are not automatically prioritised when established tumour-biological evidence is more decision-relevant.

The report prioritises unresolved issues that may change the treatment sequence before purely exploratory additional testing. A live analysis would additionally verify the current guideline version, regional approval status and active clinical trials at the time of assessment.

5. Tumour-board questions, sources & final assessment

Questions for the treating team / tumour board

• Is the disease still appropriate for endocrine-based treatment or is chemotherapy/ADC sequencing more appropriate?

• Which study populations best match the documented previous treatment?

• Which molecular results are still missing and could change the next line?

• Are pulmonary, hepatic or other safety factors relevant to the options under discussion?

Selected evidence anchors

• Current international breast-cancer guidelines and regional regulatory information.

• INAVO120, CAPItello-291 and DESTINY-Breast06 as evidence anchors for the demonstrated biomarker/sequence questions.

• Original pathology, molecular reports and current imaging remain mandatory for a live case.

Final assessment

The value of the report lies not in an automated treatment recommendation, but in a transparent connection between diagnostics, patient context and evidence. It shows where an option matches well, where important differences from the study population remain, and which information is still required before a medical decision.

Clinical Review Required

Medical Evidence AI provides evidence synthesis and decision support. It does not replace diagnosis, prescribing, multidisciplinary review or treatment decisions by qualified medical professionals.