Laboratory Testing Patterns in Patients With Breast Cancer Treated With CDK4/6 Inhibitors: A Multi-Country Electronic Health Record Study From the UK, Germany, and Japan

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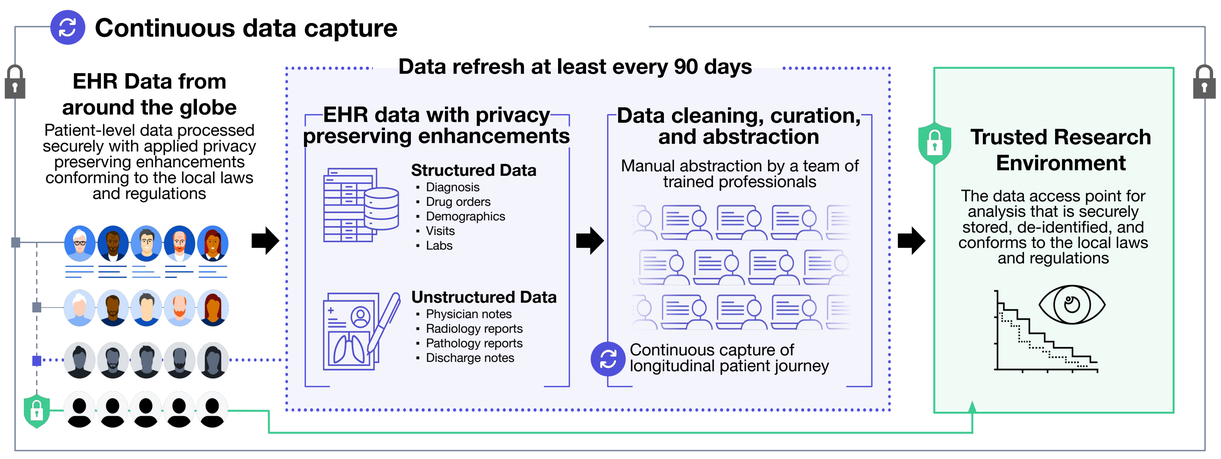
Background

- Laboratory monitoring, such as liver function testing (LFTs), is essential to detect adverse drug events like hepatotoxicity. LFTs are recommended per label for CDK4/6 inhibitors (CDK4/6i), but the frequency of testing may differ across countries
- Electronic health records (EHRs) provide structured lab testing data that can support real-world drug safety studies
- The aim of the study was to assess the frequency of LFTs in patients with breast cancer treated with CDK4/6i using EHR data across the UK, Germany, and Japan

Methods

- **Data source:** The multinational longitudinal Flatiron Health Research Database—an EHR-derived, de-identified database comprising patient-level data originating from 2, 3, and 3 cancer centres in UK, Germany (DE), and Japan (JP), respectively, and curated via technology-enabled abstraction[1,2]
- **LFT:** ALP, ALT, AST, Bilirubin
- **Setting:** The study included patients diagnosed with locally advanced or metastatic HR+/HER2- breast cancer from January 1, 2016, to June 30, 2025, who were aged ≥18 years, were treated with CDK4/6i in the first line of therapy, and had LFT done within 4 weeks prior to start of the treatment
- **Primary outcome:** The percentage of patients with recorded LFTs across 16 consecutive 1-week intervals following CDK4/6i initiation

Figure 1. Overview of the Process for EHR-Derived Real-World Data Curation



ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase

Results

Table 1. Attrition Table

Step	Description	DE, No.	JP, No.	UK, No.
1	Females with locally advanced or metastatic breast cancer, and an initial diagnosis on or after January 1, 2011	686	356	1041
2	HR+/HER2- breast cancer, received first CDK4/6i in locally advanced or metastatic setting, on or after January 1, 2017	223	141	190
3	At least one LFT within the four weeks prior to their CDK4/6i start date	177	123	178

Table 2. Demographics of Patients Included in the Study

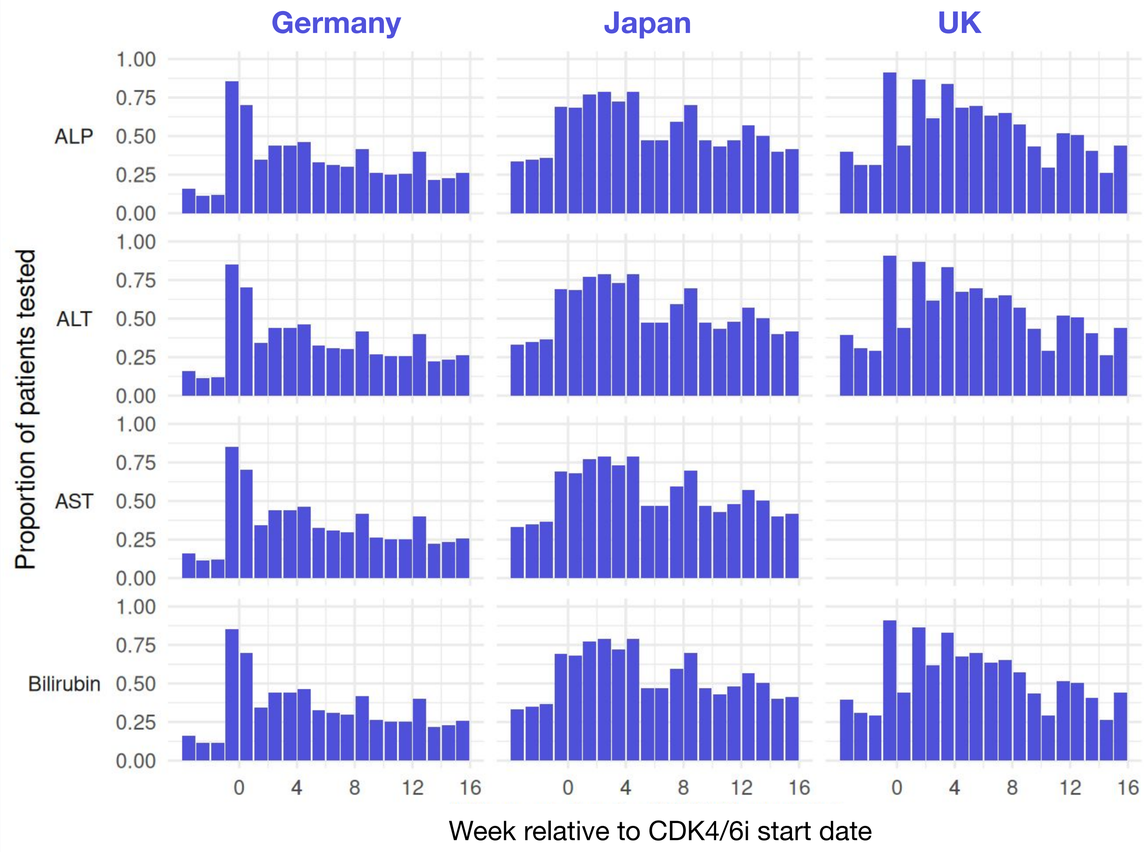
Characteristics	DE cohort (n = 177)	JP cohort (n = 123)	UK cohort (n = 178)
Age at CDK4/6i therapy start, median (IQR), y	69 (56, 78)	61 (51, 69)	57 (48, 67)
ECOG, No. (%)			
0	20 (59)	17 (53)	75 (43)
1	15[a] (8)	15[a] (12)	80 (46)
2+	≤10	≤10	18 (10)
Unknown	143	91	5
Time from advanced diagnosis to CDK4/6i treatment, months	2 (1, 6)	2 (1, 3)	2 (1, 5)
CDK4/6i drug received on start date, No. (%)			
Ribociclib	35[a] (20)	0 (0)	57 (32)
Palbociclib	136 (77)	40 (33)	107 (60)
Abemaciclib	≤10	83 (67)	14 (7.9)
State at CDK4/6i start date, No. (%)			
Metastatic	175[a] (99)	115[a] (93)	175[a] (>99)

IQR, interquartile range; [a]value rounded

Results (continued)

- **Participants:** The study population included 177, 123, and 178, patients from DE, JP, and UK, respectively, the majority of whom received palbociclib (UK and DE) or abemaciclib (JP)
- **LFT rates (any test):** DE: decreased from 91% (weeks 1-4) to 80% (weeks 5-8) and 71% (weeks 9-16). JP: consistently >90% across all 16 weeks. UK: >90% until week 8, then >80% until week 16

Figure 2. Proportion of Patients Tested Each Week



Frequent lab testing in structured EHRs of patients treated with CDK4/6i supports utility for **safety surveillance** of lab-based **adverse events**

Future Directions

- Support the integration of routine laboratory data into large-scale, real-world evidence generation frameworks
- Expand the use of real-world data in lab-based identification of adverse events to enhance pharmacovigilance and drug safety monitoring
- Promote global collaboration to harmonise EHR-based research methodologies

References

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2. Adamson B et al. ESMO Real World Data Digit Oncol. doi.org/10.1016/j.esmorw.2025.100113

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