Development of Oncology EHR-Derived RWD in Europe and Japan

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Background

- High quality, recent, oncology real-world data (RWD) sources with clinically meaningful depth and completeness in Europe and Japan have previously been limited.
- Our objective was to develop oncology datasets for retrospective and prospective research.

Methods

- **Data:** Electronic health records (EHR) sources include both structured and unstructured information (eg, clinic notes, pathology reports)
- **Sites:** Include a range of regionally relevant cancer care providers (ie, NHS Trusts in the UK, hospitals and community clinics in Germany, cancer centers in Japan)
- **Models:** Pre-specified variables (eg, Eastern Cooperative Oncology Group [ECOG] performance status, biomarker test result definitions) and outcomes (eg, mortality, progression, response) have 90-day recency
- **Governance:** De-identification processes and anonymization strategies are tailored to each jurisdiction
- **Analysis:** Patient-level data is made secure for analysis in a trusted research environment (TRE) allowing pooling of individual-level data across countries

Results (continued)

We assessed the fitness for purpose of the Flatiron Health data using the ISPOR SUITABILITY checklist as a framework

Data sources from our oncology healthcare networks around the world
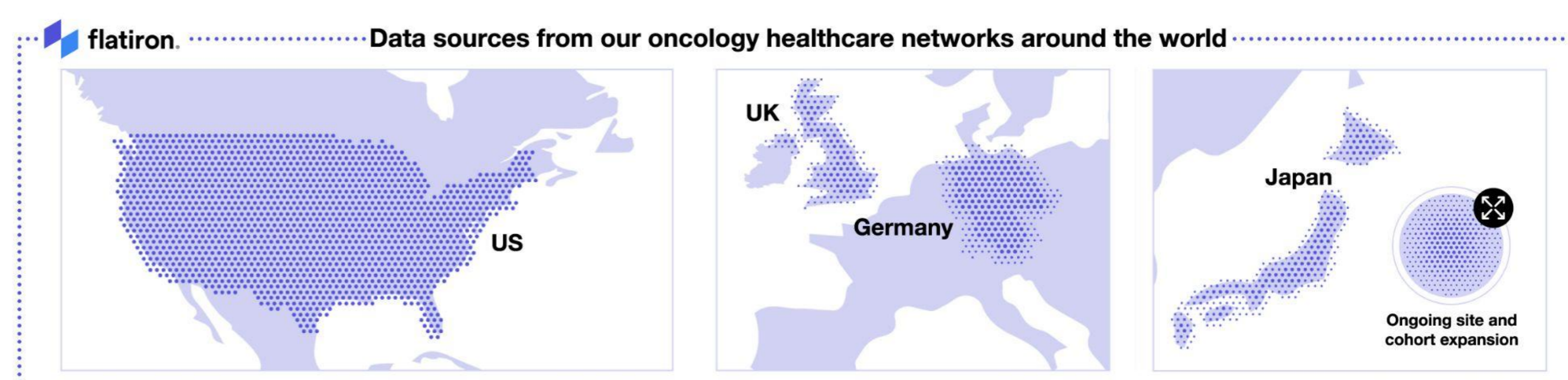
Disease-specific common data models enabled **curation with clinical depth, harmonized** across four countries
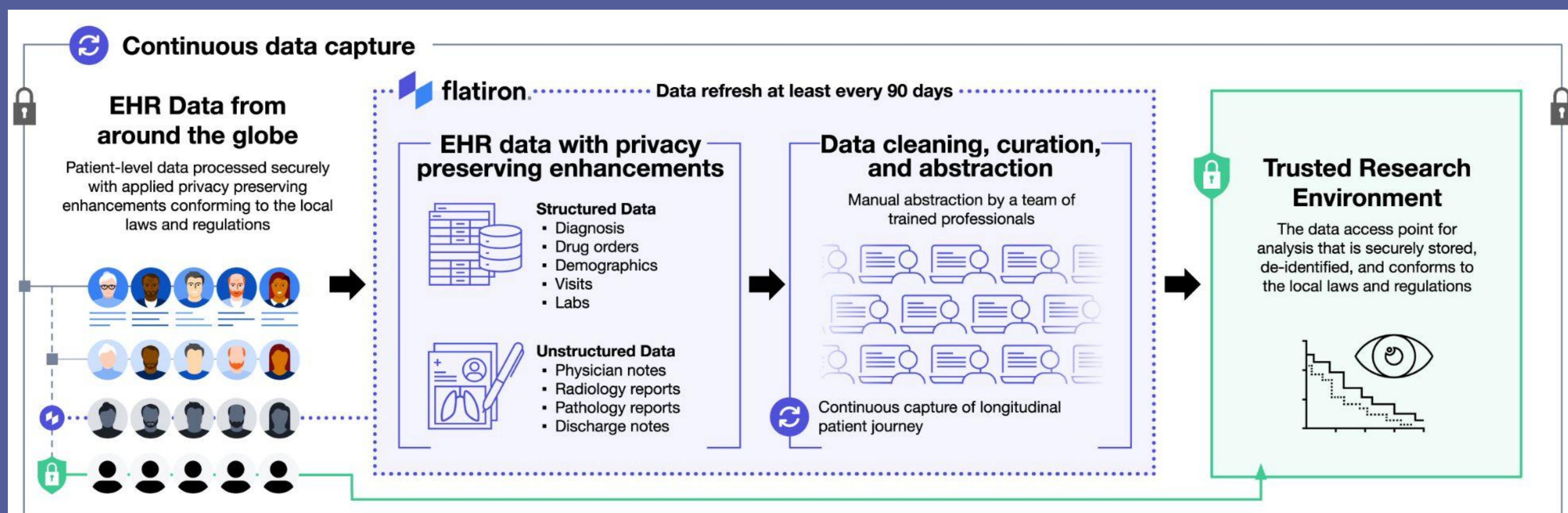
Results

Time Period: Retrospective data from patients diagnosed with cancer between January 2016 and December 2023, and across disease stages, was successfully curated into research-ready datasets. Early insights into follow-up through March 31, 2024 are presented here. Pre-specified prospective follow-up of cohorts began in January 2024

Insights in the UK and Germany

- The prevalence of biomarker positivity in Europe breast cancer (n = 402) was: HER2+ 14%, ER+ 79%, and PR+ 65%. The prevalence rate in Europe of biomarker positive results (as a percentage of those tested) in NSCLC (n = 730) was: EGFR+ 10%, PDL1+ 54%, KRAS+ 37%

Insights in Japan and the US

- Among patients in Japan with stage IV colorectal cancer (n = 417) and stage IV gastric cancer (n = 428), we found 3.1% and 3.5%, respectively had an ECOG score of 2 or above at the time of their first treatment
- Equivalently, among patients in the US with stage IV colorectal cancer (n = 19 288) and stage IV gastric cancer (n = 5 722), 11% and 12%, respectively had an ECOG score of 2 or above at first treatment.

Future Directions

We demonstrated the feasibility of a secure and compliant environment to curate and combine real-world, patient-level oncology data across country borders for analysis that include Europe and Japan in addition to existing US data. Flatiron Health multi-national, EHR-derived datasets were developed with the intention of being fit-for-purpose for treatment comparative-effectiveness research
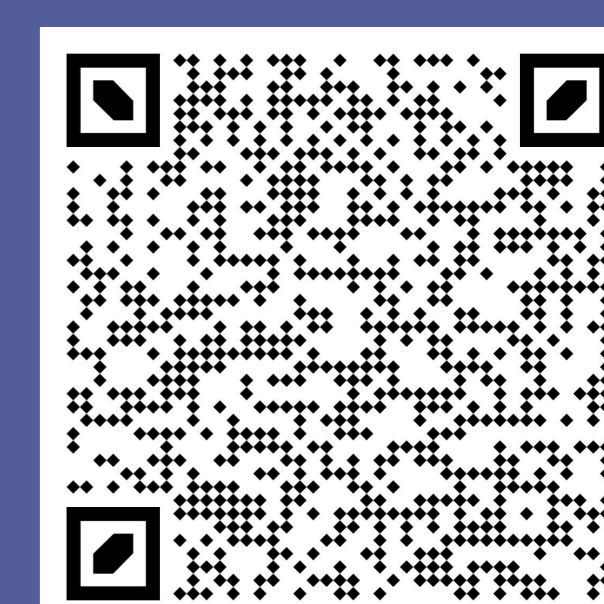
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