

EVOLVE: An Ambispective, Patient-Centered, Real-World Early-Stage Breast Cancer Registry in the United States

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Background

Breast cancer ranks as the most diagnosed cancer (excluding non-melanoma skin cancers) and is the second leading cause of cancer-related mortality in women in the United States (US)¹. Most breast cancers are diagnosed in early stages (i.e., stages I – III)^{2,3} collectively referred to as early breast cancer (eBC). With the increase in early detection and adoption of modern treatments, the 5-year survival rates of patients with eBC have significantly improved^{1,2}, but the risks of recurrence and long-term treatment related sequelae remain as concerns for many patients³.

Contemporary real-world data are needed to understand current diagnostic testing pathways, treatment patterns, patient experience, toxicities, impact on quality-of-life, and determinants of treatment choices to:

- better characterize eBC care and knowledge gaps
- establish important hypotheses to test in prospective trials
- improve both treatments and outcomes for patients.

Specific Aims

The EVOLVE cohort aims to:

1. serve as a contemporary real-world database relevant to understanding demographic and clinical characteristics, social determinants of health (SDoH), diagnostic testing pathways, treatment patterns, and clinical outcomes, including AEs
2. generate real-world evidence (RWE) for evaluating and improving demographic and SDoH differences in care management, outcomes, and patient experience during and following eBC diagnosis and treatment
3. evolve as the eBC landscape changes to continuously address new research questions.

Eligibility Criteria

Patients who meet the following criteria will be included in the EVOLVE cohort:

- have stage I-III breast cancer at the time of diagnosis
- diagnosed for the first time with eBC ≤3 years before enrollment
- onboarded to the PicnicHealth Research Platform after the following:
 - signed informed consent to participate
 - signed HIPAA authorization for medical record collection, and
 - provided ≥1 provider or site of care so that PicnicHealth can initiate retrieval of medical records.

Study Design

Data Source

PicnicHealth and AstraZeneca are collaborating to build a real-world observational database of patients with eBC. The database will be composed of de-identified medical records data supplemented with patient-reported outcomes (PROs), including patient-reported SDoH.

- disease-specific data is abstracted from medical records using PicnicHealth’s human-in-the-loop machine learning abstraction platform, including but not limited to labs, biomarkers (e.g., BRCA, PALB2), medications, family history, comorbidities, and procedures.
- patient-reported data, including but not limited to SDoH, symptoms, quality of life, and treatment experience will be collected through surveys.

Patients will have access to their records in the form of a searchable and shareable digital timeline. Patient information will be confidential and anonymized.

Patient Recruitment

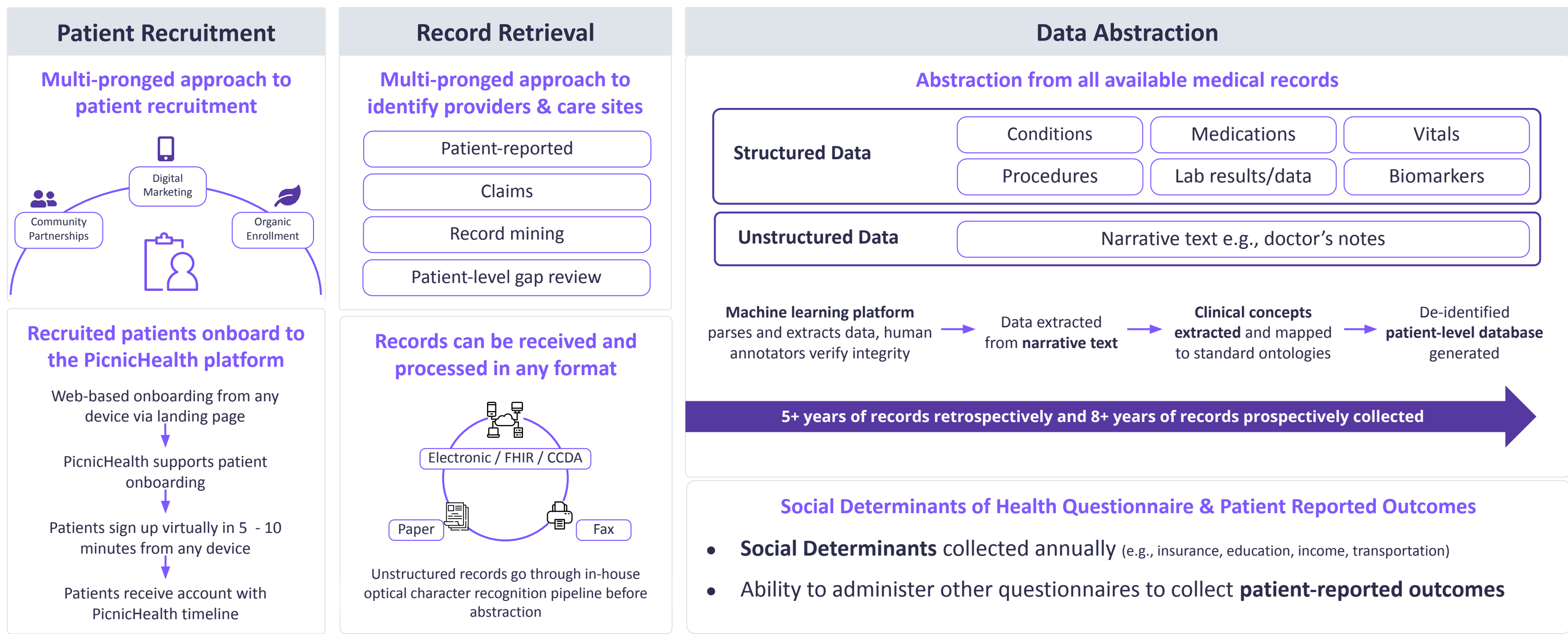
To maximize accessibility and diversity of participation, patients are recruited directly and not limited by sites of care. Patients are recruited remotely from multiple channels, including but not limited to digital marketing campaigns and community partnerships. Participating patients consent to participate in research and sign HIPAA authorization for PicnicHealth to collect their medical records from all providers and sites of care in the United States, including:

- all available retrospective medical records in any format
- ongoing, prospective records following enrollment.

Patient Follow Up

The first patient consented for eligibility screening in May 2023. Patients will be followed for ≥8 years or until withdrawal or death, whichever occurs first.

Figure 1. Study design



Present and Target Accrual

Present

As of October 2023, 2,693 patients have onboarded to the PicnicHealth platform and will be screened for eligibility for enrollment into the EVOLVE cohort.

Target

At least 3,000 patients will be enrolled in the EVOLVE cohort.

Statistical Methods

The creation of this database aims to create a data cohort to enable RWE generation for current and future research questions. Initial analyses will summarize the cohort overall and by pre-determined subgroups using descriptive statistics:

- demographics (e.g., race, ethnicity)
- SDoH (e.g., insurance, education, income)
- clinical characteristics (e.g., stage, hormone receptor status, biomarkers)
- treatments (e.g., surgery, chemotherapy, radiation)
- healthcare resource utilization (e.g., hospitalizations, outpatient visits)
- eBC outcomes (e.g., recurrence, progression)
- patient experience (e.g., health-related quality of life).

Future analyses include, but are not limited to evaluating the impact of key exposures, such as SDoH, on

- treatment and diagnostic pathways
- treatment endurance
- clinical outcomes
- PROs.

All analyses for future independent research studies will be prespecified in study-specific statistical analysis plans.

References

1. American Cancer Society. Cancer Facts and Figures 2023. Atlanta, Ga: American Cancer Society; 2023.
2. American Cancer Society. Breast Cancer Facts & Figures 2022-2024. Atlanta: American Cancer Society, Inc. 2022.
3. Nelson DR, Brown J, Morikawa A, Method M. Breast cancer-specific mortality in early breast cancer as defined by high-risk clinical and pathologic characteristics. PLoS One. 2022;17(2):e0264637. Published 2022 Feb 25. doi:10.1371/journal.pone.0264637