HARVARD UNDERGRADUATE CBE

# Life Sciences Think Tank: FemTech & Women's Health Technology

CBE | Fall 2025


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# Team Introduction

Harvard CBE represents a diverse range of backgrounds and interests. We are excited to present the final results of our think tank project looking into the women's health & FemTech market.

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# Project Overview

Over the course of eight weeks, our team investigated women's health technology and the FemTech industry. We highlighted key economic, regulatory, and social challenges with the approval and implementation of current technologies and looked at the current and future impacts of these products.

After thoroughly analyzing current major players in the FemTech market, synthesizing ongoing scientific research, and analyzing key bottlenecks, the team outlined strategic considerations for potential startups, high-efficiency partnerships, and regulatory compliance.

Market Research & Funding Landscape

Critical Analysis of Current Solutions

Challenges & Bottlenecks

Strategic Recommendations

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# Market Research & Funding Landscape

With increasing interest in women's health and FemTech applications, understanding the current market, focus areas of product offerings, and funding opportunities lays a stable foundation for an up-and-coming industry.

## Section 1: Market Overview

Section 2: Current Applications

Section 3: Funding Landscape

Section 4: FemTech Startup Comparisons

# Overview & Market Analysis

The U.S. FemTech market is currently dominated by businesses specializing in pregnancy, nursing, reproductive health, contraception, and menstrual health, and it continues to experience significant growth in partnerships and ventures.

## Comparative Context

### Recent Growth of FemTech

Between **2015** to **2024**:

- The **number of ventures** in the FemTech market **grew by 3.2 times**, compared to an increase of 2.8 times in the overall digital health market.
- FemTech **partnerships** were over **15 times higher** in 2024 compared to 2015, while digital health was 11.

### Global Investment Comparisons

- The **United States** is a leader in FemTech investment, totaling **$11.2B** to date, followed by **Israel**, the **UK**, **France**, and **Switzerland**.
- Within the **US**, **California** had the highest amount of FemTech funding of any U.S. state in **2024**, followed by **New York** and **North Carolina**.

### Key Takeaway

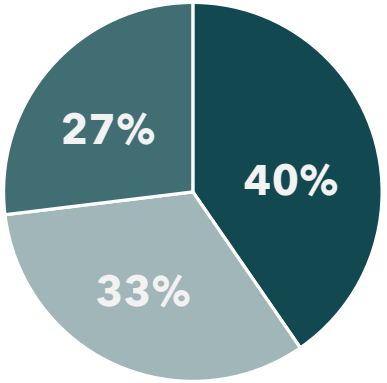
The United States is a **global leader** in the FemTech market for investments, ventures, and partnerships.

### FemTech Market Share by Segment

**21%** Pregnancy & Nursing

**17%** Reproductive Health & Contraception

**14%** Menstrual Health




**$3.0B**

The **global menopause care segment** generated a revenue of **$3.0B** in **2024** and is expected to reach **7.45B USD** by **2030**.

**+10%**

The majority of FemTech market leaders who were surveyed in 2021 projected a **sales growth** in their companies of **over 10 percent** in the next year.

**$218B**

By 2027, it is forecast that the **highest valued** sector of FemTech will be **chronic** conditions at **$218B** USD, which include diseases such as **endometriosis**, **ovarian cancer**, and **polycystic ovary syndrome**.

**$171b**

**Reproductive health** is forecast to have the **second-largest share** in the FemTech market and will continue to be an important part of the industry.

*FemTech Health*, *Grandview Research*, *Statista (I)*, *Statista (II)*, *Statista (III)*

# Market Analysis, Drivers, and Barriers

The FemTech market provides massive opportunity as society overcomes stigma towards women's health while digital, online, and AI products become increasingly relevant in younger populations like Millennials and Generation-Z.

## Market Size and Growth

- The US far surpasses other nations in the investments received, **taking in $11b as of 2022,** followed by Israel at only $1.4b.
- **55%** of worldwide FemTech **ventures focus on Gynecology and Oncology**.
- By subsector, pregnancy and nursing (20%) companies lead in NA. Reproductive health & contraception (17%) comes in second, then general healthcare (14%), menstrual health (13%), pelvic & uterine healthcare (9%), and sexual health (9%).
- Annual FemTech venture funding worldwide **decreased from 2021 to Q1 2025**.
- 42% of FemTech digital health funding is supporting medical diagnostics.
- Growth in the past decade stems mainly from **partnerships over ventures.**

## Drivers

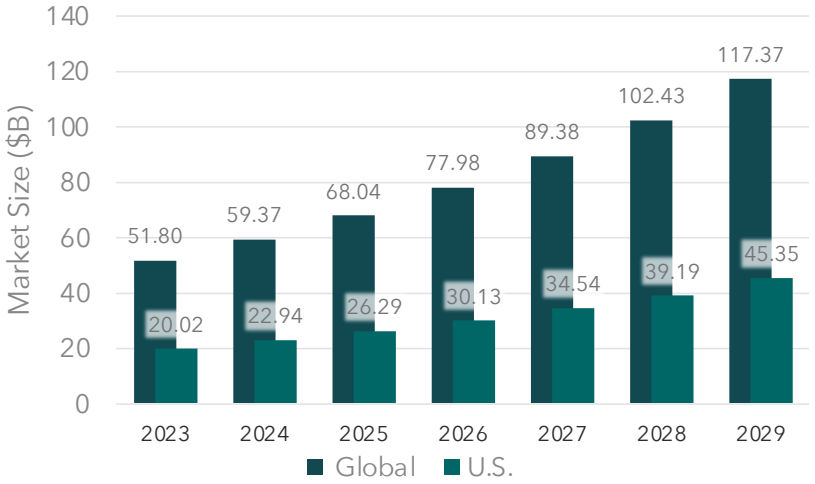
- Social movements to **destigmatize menstruation, menopause, and sexual health and awareness of non-reproductive diseases** increased market interest.
- Healthcare consumerization trends boost digital diagnostic products.
- Google Trends search data showed increased interest starting during Covid-19,
- In 2023, the **White House committed over $800m to** women's health research.

## Barriers

- On a review platform with 90% male users, **female-focused products showed 40% less growth**, demonstrating entrenched sexism and feedback sampling bias.
- Startups struggle to hire top talent, with **80% of people applying for startups being men**, while men are 10% less likely to apply for a female-focused startup.
- Female-focused ideas attracted **25% fewer employees**, and those who were interested had, on average, **30% less work experience**.

*Forbes, HBS (I), HBS (II), Precedence Research, Statista, Statista (II), White House*

## Predicted FemTech Market Size




- The FemTech market is growing at a **CAGR of 14.61%**.
- NA led the global market with the highest market share at 38.64% in 2024. This is reflected in the graph above although it does not account for changes in regional market share.
- **47% of R&D centers and over 50% of FemTech companies are located or based in North America.**
- Data is estimated from 2024-2028 and forecasted in 2029.

# Evidence of Women's Underrepresentation

Persistent underrepresentation of women in heart-disease, oncology, and drug-safety studies reveals how bias shapes evidence and how targeted reforms like sex-specific dosing and inclusion mandates are closing (and exposing) the gaps.

## Cardiovascular / Coronary Revascularization Trials

- In a review of 1,079 **cardiovascular trials** from 2017–2023, among 1,396,104 participants, **only 571,641 (≈ 41%) were women**.
- The **median female-to-male ratio** was **especially low** in trials of arrhythmia (**0.50**), coronary heart disease (**0.39**), acute coronary syndrome (**0.32**), and heart failure (**0.51**).
- When benchmarked to disease prevalence, **participation-to-prevalence ratios (PPRs)** for women were **< 1 in key domains** (e.g. CHD ~ 0.66, ACS ~ 0.79, stroke ~ 0.74), signifying underrepresentation relative to disease burden.
- Over the decades, **underrepresentation has worsened**: a broader review observed that between 1992 and 2022, the proportion of **cardiovascular trials that underrepresent women increased** (from ~ 48.3% to ~ 70.5%), with median female enrollment around **~ 29.9%**.
- Trials led by **academic institutions tend to enroll more women** (F:M ~0.97; PPR ~1.12) vs industry (F:M ~0.57) or government sponsors (F:M ~0.34).

## Zolpidem (Ambien) – Sex-Specific Dosing After Market Approval

- **Early clinical trials didn't reveal sex differences**; later pharmacokinetic studies showed women have **~35% lower apparent clearance for zolpidem compared to men**.
- Because of slower elimination and higher residual morning levels in women, the **FDA in 2013 halved recommended starting dose for women to reduce risk of next-morning impairment**.
- A 2024 in **silico (PBPK) modeling study** affirmed that women have **higher systemic exposure and slower clearance;** suggests even the halved dose may still not optimally align with female pharmacokinetics.
- Regulatory and academic commentary characterize **zolpidem as a landmark case**: the first widely accepted sex-based dosing label and a **"sex-difference fact" created via postmarket corrections**.
- Critics note that, despite the FDA action, **no other regulatory authority internationally has uniformly adopted sex-based dose reductions**, so global consistency remains lacking.

## Oncology / Cancer Drug Trials

- A study of 1,650 U.S. oncology trials (2008–2020) found that **women were underrepresented relative to disease incidence in many tumor types** (e.g. kidney, bladder, stomach, anal).
- More broadly, **sex disparities in cancer drug efficacy and toxicity are evident**: many trials lack sex-stratified analyses; **reduces ability to detect differential responses** or adverse events in women vs men.
- Because many **oncology trials enroll fewer women**, **statistical power is limited** for sex-specific subgroup analyses, making extrapolation of efficacy/safety to female populations less reliable.
- The oncology research community is advocating for **mandatory sex-stratified outcome reporting**, trial enrollment **quotas by sex**, and regulatory pressure to enforce these standards.
- Some retrospective meta-analyses show that **adverse event rates and pharmacotoxicity differ by sex**; underscores importance of balanced enrollment to detect those differences.

*AJMC, Frontiers, Henry Ford Health, JAMA, SagePub, Science Direct I, Science Direct II, Springer Nature*

# Market Research & Funding Landscape

With increasing interest in women's health and FemTech applications, understanding the current market, focus areas of product offerings, and funding opportunities lays a stable foundation for an up-and-coming industry.

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**Section 2: Current Applications**

Section 3: Funding Landscape

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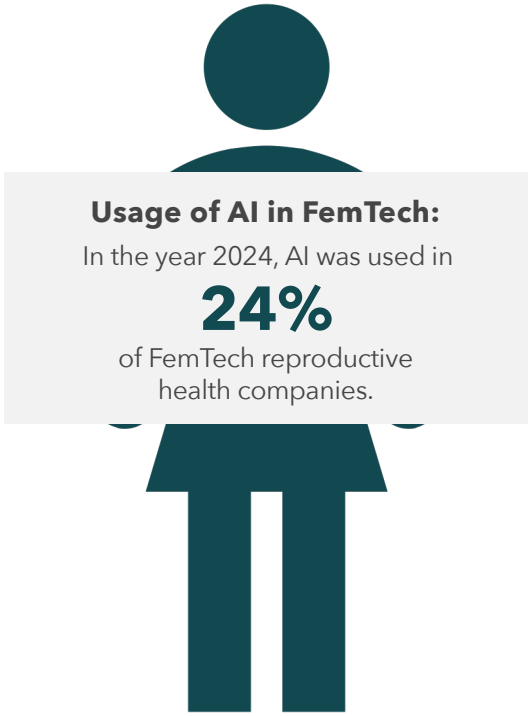
# Current FemTech Applications

FemTech applications are split into three main areas: chronic condition monitoring, wearable devices, and telehealth platforms. These work to provide diagnosis, management, guidance, and health recommendations for many conditions.



**Usage of AI in FemTech:**

In the year 2024, AI was used in

**24%**

of FemTech reproductive health companies.

## Chronic Condition Monitoring

- **Endometriosis** is a condition where tissue similar to the lining of the uterus grows outside the uterus, resulting in extreme **pain** and **infertility** for **1 in 10** women.
- A **diagnosis tool** developed by FemTech company **Hera Biotech** developed the world's **first non-surgical test** for **definitive diagnosis** and **staging** of **endometriosis** called **MetriDx**.
- Similarly, **Phendo** is a **free research app** that helps women **track**, **manage**, and **understand** endometriosis and **self-management strategies**.

## Wearable Devices and Smart Trainers

- **Wearable devices** in FemTech address various issues **specific** to women's health.
- General female health **tracking bracelets** such as ones from **Avabracelet** and **OvuSense** provide **hormone monitoring**, **ovulation prediction**, and **temperature-based tracking**.
- For women experiencing **menopause**, **thermal wearables** track **hot flashes**, **variations** in **heart rate**, **sleep disruptions**, and **hormone fluctuations**.
- **Pregnancy monitoring** devices track **fetal movement**, **contractions**, and **heart rate**.

## Telehealth and Tracking Platforms

- **Telehealth** apps like **Pregnancy+** and **What to Expect** offer week-by-week **guides** on **fetal development**, **nutrition tips**, and **safe exercise routines** for expecting mothers.
- **Mental health** platforms such as **Maven** offer **tailored support**, connecting users with **therapists** to address issues like **postpartum depression**, **anxiety**, or **child loss**.
- While there are various types of **specific FemTech** apps available, platforms typically include **health recommendations**, **symptom trackers**, and **educational resources**.

*Binariks*, *FemTech Health*, *FemTech World*, *Grandview Research*, *Reanin*, *SPH UNC*

# Diagnostic Delays

Diagnostic delays remain highly prevalent despite advocacy efforts to decrease stigma around women's health and increasing health care provider awareness; this results in years of diagnostic delays and uncertainty for women.

## Causes

- Social stigma is key with a 2020 UN study finding **90%** of people in the world **harbor some level of gender bias** towards women.
- Misdiagnosis also impacts women's health as **women are 66% more likely to receive a misdiagnosis than men**, ultimately contributing to increased time to diagnosis (TTD) and creating false hope for patients.
- For PCOS, over 1/3 of women reported >2 years and **≥3 healthcare professionals before diagnosis**. The average diagnosis takes 4.3 years.
- Outdated healthcare standards are another cause, while menopause occurs at age 52 on average, in one study over 50% of women ages 40-64 experienced symptoms related to perimenopause or menopause, yet **only 8% of women had received a diagnosis**.
- On average, women receive **cancer diagnoses 2.5 years after men**, and diagnoses for metabolic diseases like diabetes **4.5 years later**.

"My family lives in a town, **relatively far away from a large hospital**. If there is a small problem, I usually go to the town's health center to get some medicine prescribed and take it. **It is not convenient to go to the county hospital to see a doctor.** The public buses to the county are available only in the morning. However, I also have to cook breakfast for the child in the morning."

"So now I've got Crohn's [disease] on top of everything else. And the other thing with Crohn's is of course, it's affected by stress, so I can get a flare from stress. I can get a flare from getting a cold or from getting gastro or things like this. So, **there is a real direct connection between my physical and mental health** with that one. And so that's been really hard to deal with, because again, generally, the history is, is that **I have to fight for them to investigate things**."

- **Geography:** Large differences in endometriosis diagnosis time were seen between countries, with the **US having the lowest overall** time. This US's robust healthcare systems may contribute to lower delays.
- **Market Expansion:** With the global menopause market is expected to expand from $17.66 billion in 2024 to **$27.63 billion by 2033**. Higher growth is expected in North America, with a CAGR of 4.9%
- **Decade-long Delays:** Diagnoses for endometriosis can take anywhere from **5 to 12 years** for women, mostly **due to lack of provider awareness** and lack of a standardized approach.
- **Consequential Costs:** Endometriosis cost nearly $9,000 or 40% more when diagnosis takes 1-3 years and over $13,000 more for 3-5 year-long diagnoses due to more often **emergency visits and hospitalizations.**

*BMJ Open*, *Evernorth*, *GlobeNewswire*, *Journal of Women's Health*, *NBC News*, *PubMed (I)*, *PubMed (II)*, *PubMed (III)*, *PubMed (IV)*, *Washington DC Injury Lawyers*, *Yale Medicine*

# Impact of Diagnostic Delays

Diagnostic delays are common in women due to a variety of societal reasons and gender stereotypes with dangerous implications on women's mortality and unrecognized economic deficit that support the need for FemTech advancement.

## Women's Health

- Women suffer **fatal medicine and health events** 36% more than men and maternal and postpartum death rates continue to rise.
- Women's health research is focused on **less anatomically prevalent** conditions, and medicine is **less safe** for women than men.
- Women are **5.7% more likely to die** in a hospital and have an **increased mortality rate** from undiagnosed underlying conditions.
- Women are **66% more likely** to receive an **incorrect medical diagnosis or remain undiagnosed** by a medical professional.
- Beliefs about the severity of symptoms or an expected ability to "deal with pain" means up to **8 out of 10 women ignore symptoms**.

## Funding

- An estimated **one trillion dollars** is lost each year economically due to **9.9% less time working** or otherwise dealing with health issues.
- **45% of the health burden** occurs during the **typical years of employment** (between the ages of 18 and 55).
- Relevant research is **not funded or conducted** because of the perceived lack of prevalence based on limited research.
- A larger portion of the 800,000 people who **die or become permanently disabled** from **misdiagnosis** in the U.S. are women.
- Data is **not reported or collected properly** about the prevalence of diseases (i.e. endometriosis affects 1-10% of the population).

*Alcimed, Ellingrund et. al., Peters*

# Case Study: AOA Dx

AOA Dx's ovarian cancer diagnostic tool AKRIVIS GD gained media attention after early studies suggest greater accuracy for detection through a blood test that looks for lipids and proteins using an algorithm trained from patient samples.

## AOA

- **Founded in 2020**, AOA Dx focuses on **early-stage ovarian cancer detection** through its GlycoLocate platform and AKRIVIS GD technology.
- AOA Dx has grown from 3 founders to a total of 12 employees, and opened their first headquarter lab **facilities in Denver, CO** in Jan 2024.
- The start-up received **overwhelmingly positive responses from VCs and angel investors**.

## Market Need

- **Only 15% of ovarian cancers are found early** despite recent large-scale trials showing over 90% of women experience symptoms for many months.
- Symptoms are often attributed to other causes. Therefore, **cancer isn't typically diagnosed until Stage 4**, which has a 5yr survival rate of <20%.
- **By 2035** new ovarian **cancer cases will increase 55% and deaths by 67%** if not detected earlier.

| | |
|---|---|
| **AKRIVIS GD** | • AKRIVIS GD utilizes multi-omic technology and advanced computational biology to create a **liquid biopsy test** that will accurately detect ovarian cancer.<br>• The **blood test** is a biomarker technology and AOA Dx's lead asset under its **GlycoLocate platform**, which pioneers in the field of Glycolipids within diagnostics. |
| **Clinical Progress** | • AOA Dx **published in multiple research academic journals**, including a 2021 proof of concept study, 2023 diagnostic biomarker study, and 2025 OVERT clinical trial.<br>• Though both studies were published in prestigious journals and peer reviewed but they are **still applying for regulatory approval** in the United States and Europe. |
| **Funding** | • The company was **awarded over $25m** after being backed by Y Combinator, Good Growth Capital, Avestria Ventures, and Joyance Partners, among other VCs.<br>• Its scientific collaboration partner, Professor Uri Saragovi of McGill University, was **awarded a $650k CAD grant** for further development of AKRIVIS GD. |
| **Reception** | • AOA Dx has maintained **interest and media coverage** from the BBC, University of Colorado Anschutz,, the Independent, the Guardian, Femtech Insider, and CBS News as recent as May and Aug of this year, suggesting promising potential.<br>• Data was shown at the **2025 American Association for Cancer Research** meeting. |

### Key Takeaway

AOA Dx and its partnering institutions continue to break technological barriers in ovarian cancer through research and development of **critical biological-based devices, software models, and studies** by leveraging investor support, **earning innovation awards**, and **creating awareness** of diagnostic challenges.

*AOA Dx (I), AOA Dx (II), AOA Dx (III), AOA Dx (IV), Forbes (I), Forbes (II), The Guardian*

# Market Research & Funding Landscape

With increasing interest in women's health and FemTech applications, understanding the current market, focus areas of product offerings, and funding opportunities lays a stable foundation for an up-and-coming industry.

# Funding Landscape, Gaps, and Barriers

Despite growing investor interest, FemTech remains underfunded, niche, and shaped by persistent gender-based disparities in U.S. venture capital, where specialized investors are already scarce and limited in capital.

## Specialized Investors Are Scarce

- A few **niche women's health funds** (e.g. Amboy Street, Goddess Gaia, RH Capital) are forming and investing in reproductive health, menopause, sexual health, etc.
- Such funds remain rare, with **limited capital** under management **compared to general healthtech VCs**.
- These specialized funds often **lead or co-lead early rounds** (seed, pre-Series A), where **risk is higher and domain knowledge matters**.

## FemTech Still Small Allocation for VCs

- **Top general VCs** (Sequoia, General Catalyst, Emerson Collective) have **backed leading U.S. FemTech firms** (e.g. Maven Clinic, Midi Health).
- For these generalist firms, **FemTech represents a small fraction** of their overall **health/tech portfolio** (often < 5 % of health deals).
- **Generalist VCs** may show up in **larger rounds** or **later stages**, but don't dominate early stages.

## FemTech Investment Underfunded

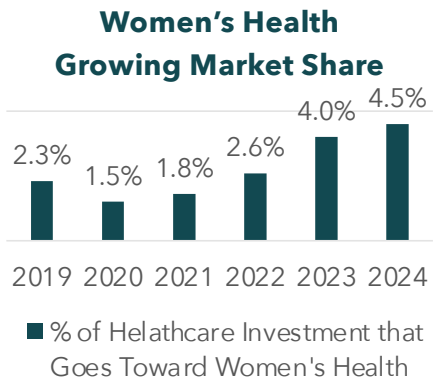
- **United States VC investment** in women's health startups hit **$2.6B in 2024**, a **55% increase** from 2023; including adjacent women-focused conditions, the sector **totaled $10.7B**.
- Despite this, **only 2.3% of all U.S. healthcare VC went to women's health** in 2024 – just $1.19B of the total.
- That **$1.19B was raised across 111 deals**, with an average deal size of $10.71M, reflecting ongoing **early-stage concentration**.

## FemTech Funding Disparities & Biases

- **70% of FemTech startups** are **founded by women**, yet **male-only teams** raised **$731M vs $408M** for female-only teams across the same period.
- **Average raised:** all-male teams received $9.2M, female-only teams $4.6M. In 2023, the **gap briefly flipped**: female-led FemTechs raised $1.8M more.
- **Teams with women** receive just **28% of FemTech VC funding**; penalized for using terms like "empower," unlike **male peers using the same language**.

## Methodology

The chart displays the **annual % of U.S. healthcare VC investment allocated to women's health startups** – including FemTech, diagnostics, therapeutics, and chronic conditions – based on Silicon Valley Bank's 2024 Women's Health Innovation Report.




*Ellty*, *Nasdaq*, *Silicon Valley Bank*, *Sifted (I)*, *Sifted (II)*, *The Guardian*

# Top FemTech Investors in the United States

Both FemTech specific investment funds, like Portfolia, and general investment groups, like Box Group and Groove capital, have contributed to successful FemTech ventures that have begun to address gendered health disparities.

**Box Group**

- Box Group is a **large early-investment group** that has funded FemTech start-ups like Nourish, Polemlo Care, Maven, and SuppCo.
- This group aims to fund ventures in **specific markets**, like FemTech, that cover areas that have not previously been capitalized upon.
- It has participated in **women's health-specific founder matchups**.

**Groove Capital**

- Groove Capital is an **early-stage investment company** that support the rounds of startups like Pelva Health through ventures like the **2025 angel investment circl**e specifically for women and women's issues
- Based in Minnesota, many of the startups funded by Groove Capital are from Minnesota but have **nation-wide implications and interests**.

**Portfolia**

- Portfolia is **an investment fund** that has invested in over 46 FemTech startups like EveryHealth, FEMDx, Hera BioTech, and OsteoBoost.
- They are the **largest investor** in women's health with the Women's Health Fund IV model and over **105 investments**.
- They host **FemTech-specific conferences** and educational events.

### Issues and Inequalities Facing FemTech Investments

- Only **2% of funded** health-related ventures surround women's health.
- Women make **80% of healthcare decisions**, but women-specific conditions are consistently **less researched** than multi-gender or male-specific health conditions.
- Over **one trillion dollars** could be generated by **addressing the gap** in gendered research and healthcare disparities.
- Investment companies like these three that fund ventures like FemTech are vital to starting to address the **value lost by the research and funding gaps**.

*Box Group, Desmond, Ellingrud et al.*., *Groove Capital*, *Portfolia*, *Rosard*, *Solal and Snellman*

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# Comparison of FemTech Startups (I)

While women and women's health issues were long underrepresented in tech and healthcare from medical diagnostics and devices to menstruation and fertility, FemTech startups are capitalizing on this market gap more than ever.

## NextGen Jane

- Founded in 2014, NextGen Jane focuses on obstetric and gynecological health, notably **collecting over 2,000 "smart tampon" kits** from women with various conditions **to generate genomic data** and improve women's health diagnoses.
- The company was awarded a **$2.2m NICHD/NIH grant** for clinical validation of a non-invasive menstrual test for endometriosis in infertility patients, their **second award for endometriosis work.**
- Clinical studies focus on non-invasive diagnosis for adenomyosis and fibroids as well as the use of **microbial biomarkers** for diagnosis.

## Flo

- The **#1 women's health mobile app** by downloads, the UK-based startup has grown to over 68M monthly active users and 5M paid subscribers since 2015.
- Its **worth surpassed $1B** in July 2024 after receiving over $200m in a Series C investment.
- A 2024 study found Flo **significantly improves menstrual health literacy and awareness**, general health and well-being, and PMS/PMDD symptom burden.
- Still, the company's **male-dominated leadership** and VC funding indicate larger investment disparities where women struggle to secure similar funds.

## Ava

- Ava is a **digital diagnostics and therapeutics** company specializing in women's reproductive health, founded in 2014.
- They have helped over **70,000 women conceive**, per an FDA news release.
- Its most famous product is a **fertility-tracking sensor bracelet** that is both cleared by the FDA and backed by rigorous clinical trials.
- Their app's **cycle-tracking technology** and **machine-learning algorithms** offer support beyond fertility, with applications in family planning, sleep and fitness, prescription medications, and stages of a woman's life.
- In 2022, Ava was acquired by **FemTec Health**, a Houston-based FemTech company.

*Ava, Bloomberg, Forbes, Flo (I), Flo (II), Flo (III), Innovation Map, PR Newswire, PubMed Central, NextGen Jane, NICHD, Yahoo*

# Comparison of FemTech Startups (II)

While women and women's health issues were long underrepresented in tech and healthcare from medical diagnostics and devices to menstruation and fertility, FemTech startups are capitalizing on this market gap more than ever.

## Bloomlife

- Bloomlife was founded in 2014, making it one of the **earliest FemTech startups**.
- Their **direct-to-consumer wearable tracker** raised a total of **$6M USD** just two years after launch and measures **uterine activity**.
- Bloomlife went quiet between 2017 to 2022, but in January 2024, the company announced that it received FDA clearance for a new **prescription-based wearable device** designed to help measure maternal and fetal heart rate.
- In September 2024, Bloomlife also announced a **partnership with Peri-Gen**, a peri-natal software company, for **real-time alerts** to physicians for high-risk patients.

## Renovia

- Founded in 2016, Renovia develops **FDA-cleared digital therapeutics for pelvic floor disorders**, including urinary and fecal incontinence, using its **leva motion-based system** and companion app.
- A 2023 randomized controlled trial **showed leva users achieved significantly greater symptom improvement than traditional Kegel** exercises; supports its clinical effectiveness.
- The company has raised over **$100M** in **total funding**, focusing on **expanding access** through clinicians and health systems for women's pelvic health care.

## Carrot Fertility

- Launched in 2016, Carrot offers a **global fertility and family-building benefits platform** covering IVF, egg/sperm freezing, surrogacy, adoption, and menopause care, now reaching **4M+ members worldwide**.
- 2024 IVF Outcomes Study found Carrot patients achieved **67% pregnancy rate and 55% live birth rate**, both >20% above national benchmarks.
- With **$116M raised** and partnerships across 130+ countries, Carrot leads employer-sponsored reproductive care, combining clinical data with personalized care navigation.

*Bloomlife, Carrot Fertility, DH Insights*

Market Research & Funding Landscape

**Critical Analysis of Current Solutions**

Challenges & Bottlenecks

Strategic Recommendations

# Critical Analysis of Current Solutions

With the identification of key areas of interest within the current FemTech industry, each presents unique requirements and challenges for implementation, which also differ on a global level, where regulations differ from country to country.

## Section 1: Overview of Implementation

Section 2: Hormone Sensors

Section 3: AI-Powered Diagnostics & At-Home Trackers

Section 4: Technical, Ethical, & Privacy Concerns

# FemTech Approval and Regulations

The FDA oversees approval and regulations for FemTech products, which largely consists of medical devices. The FDA's Digital Health Center of Excellence aims provides guidelines and recommendations for digital health device approval.

## Classification

- The FDA **classifies by product**, with categories including medical devices (MDs), drugs, vaccines, blood, and biologics, and cosmetics.
- Medical devices are further **differentiated by 16 medical specialties and Class I, II, or III status**. Class I represents devices with the **lowest risk.**
- Further subcategorization applies restrictions, protocols, and precautions to various devices. For example, **Software as a Medical Device** (SaMD) is being addressed by the International Medical Device Regulators Forum (IMDRF).
- The FDA also sorts by type, topic, and purpose.

## Process

- Classification level dictates the approval process for medical devices; **Class I devices require not premarket submission**. Drugs and biologics undergo phases of clinical testing.
- Class II devices use the **510(k)** premarket clearance pathway and prove they are substantially equivalent (SE). While Class III devices require **Premarket Approval (PMA) with scientific data.**
- **Novel devices** with low to moderate risk and no market equivalent request **De Novo** classification.
- AI/ML SaMDs follow traditional processes, but the FDA has published several guiding documents.

### Case Studies

**Natural Cycles:** A software application for contraception (SAC), the app Natural Cycles received De Novo approval as a Class II device for birth control in 2018, making it the **1st approved birth control app** in the US. It showed a typical use Pearl Index of 6.5 using **clinical data from over 15k women**.

**Womed Leaf:** On Sep 16, 2025 Womed's resorbable adhesion barrier was the 1st to receive PMA for Asherman syndrome, which causes infertility. It showed **2.4x higher probability to eliminate intrauterine adhesions (IUAs)** in its **international PREG2 clinical trial**.

### Factors for Approval

- Due to the iterative process of AI/ML, the FDA recommends a **Predetermined Change Control Plan (PCCP)** for submission.
- PCCPs dictate benchmarks for clinical success and safety with new data sets but **are not mandated or binding by law.**
- In 2021 and 2024 respectively, the FDA along with Health Canada and the UK's MHRA also developed 10 guiding principles on **Good Machine Learning Practices (GMLPs)** and **transparency for ML-enabled MDs**.
- FDA guidance clarifies standards in data integrity, algorithm transparency, and patient awareness for medical device applications.
- The PMA process for Class III devices requires **scientific and regulation documentation** that demonstrates **safety and effectiveness.** Technical, non-clinical laboratory studies, and clinical investigations sections are required.

*Biospace, BMS, FDA (I), FDA (II), FDA (III), FDA (IV), FDA (V), FDA (V), Natural Cycles, Womed Tech*

# FemTech Systemic Integration

Digital health platforms (DHPs) and technologies are being increasingly implemented to provide better diagnostic care by coordinating patient data. The most successfully implementation came through government intervention.

## Policy-level Pathways

### Successful Implementation

- Innovations like telemedicine consultations, wearable devices, mHealth apps, digital patient registries for data collection, and genomic tech aid in **identifying and shortening diagnosis time for rare diseases**.
- In 2020, **38.5%** of US adults **accessed their electronic medical records**.
- In July 2025, the Trump Administration announced at its "Make Health Tech Great Again" event **commitments from major companies** like OpenAI and Google, to promote seamless **information sharing** for care continuity and increased availability for easy patient access.
- In scaling, **detailed action plans**, focus on target function, and HCP and patient tailoring allows for more frequent and widespread use of DHPs.

## Challenges

### Implementation Barriers

- Reports and data from digital health **platforms lack control groups and self-select** for motivated individuals who actively seek out such platforms.
- **Internet access** limits the use of many devices that rely on network connection in rural areas, also contributing to decreased scope. **Less educated, minority, older,** and **low-income** adults face more barriers.
- Data isolation and ethical implications remain top challenges in AI/ML.
- **Evidence-based practices (EBPs) require 17yrs on average to be implemented into clinical practice**, slowing pace of implementation.
- Lack of effective regulation and outdated nonspecific regulation practices results in approval without data and **equivalency loopholes**.

## Case Study: Saudi Arabia and Covid-19

- Prior to the Covid-19 outbreak, **government initiatives** were launched to implement digital healthcare **as early as 2005 and 2011.**
- During the pandemic, diagnoses and E-prescriptions were aided by the **Mawid app** and **Wasfaty platform** throughout state's healthcare.
- Post-pandemic survey research shows nearly **50% of people didn't use DHPs, largely due to not needing them (72%**). Findings report supplying resources for use and patient transparency are key.

## Case Study: Denmark and E-Health

- Denmark offered **monetary incentives** for HCPs to build their national e-health systems, providing €1,500 per year with quicker reimbursement for being connected to the national healthcare infrastructure.
- This led to **government mandate that EHRs integrate on a national level**, leading to 100% of HCPS adopting the national system.
- The **Shared Medication Record** now provides complete access to a citizen's prescription records between pharmacies, hospitals, and areas.

*BMC*, *CMS*, *Healthcare Denmark*, *McKinsey*, *NCBI (I)*, *NCBI (II)*, *NCBI (III)*, *ScienceDirect*

# Critical Analysis of Current Solutions

With the identification of key areas of interest within the current FemTech industry, each presents unique requirements and challenges for implementation, which also differ on a global level, where regulations differ from country to country.

Section 1: Overview of Implementation

**Section 2: Hormone Sensors**

Section 3: AI-Powered Diagnostics & At-Home Trackers

Section 4: Technical, Ethical, & Privacy Concerns

# Hormone Sensors

Hormone sensors can be used to enable patients and doctors, especially telemedicine physicians with access to digitally collected data, to make more informed and pertinent health decisions based on collected sensor data.

## Personal Devices Versus Laboratory Tests

### Pros

They collect data **faster than humans**, are more readily available in most regions, are **always able to monitor symptoms** (or at all times being worn), are able to pick up on both **drastic and subtle changes**, and can be used to feed data back into laboratory tests or to compare laboratory tests to.

### Cons

They are **less exhaustive** in the data they detect or collect and can **leave out information** about the **exact concentration** of hormones in the blood like insulin, estrogen, testosterone, thyroid hormones, luteinizing hormones, and others that **might not be considered** in some devices.

## Consumer Takeaway

- Though technology will certainly not replace physicians in places with robust women's health care systems, it **can be a bridge in low- to middle-income countries** that have fewer healthcare providers or have populations that are **less likely to go to the doctor**.
- One monitoring technology, OvuSense, had a **69.2% acceptability rate** among surveyed women.

## Hormone Tracking Technology

### Existing Hormone Tracking Technologies

- **Lab tests**: saliva, urine, blood serum, blood spot, and temperature
- **Antenna pair system** (transmitting and receiving antennas aimed at tissues and other internal structure; traditionally done by a physician)
- **Nocturnal basal body temperature** (BBT) (collected through a smart watch or intravaginal temperature monitoring via wireless logger)
- **Adhesive patches** for external monitoring (biosensing patch, sweat collection, signal processing electronics; a more affordable option)
- **Smart clothing** (bras or in shoe soles, a typically expensive alternative)
- pH-monitoring, **wireless biosensors** (implemented in underwear, vaginal rings, or tampon surfaces; and a more expensive alternative)

### The Role of AI

- AI can be used to **synthesize and process this data** faster than medical professions or other software programs, especially from monitors that collect data constantly. Thus far, it has been **85% accurate** about **menstrual-cycle occurrences** from collected data.
- One study found that women are **less likely** to act upon the results of these tests **without consulting a doctor**, so it may be used as a **tool for primary care physicians** instead of a definitive diagnosis device.

*BodyLogicMD, CDC, Giorgini, Manikandan et. al., Moghimikandelousi et al., Vaghasiy et al. (2023), Wang and Ye*

# Case Study: Persperity Health

This biosensing technology company aims to continue developing rapid sensing and reporting technology through constant research and development of their existing wearable devices and processing software.

## Persperity

- Persperity aims to have **adaptable technology** that provides **real-time and summative feedback** to users though
- The company aims to have all women able to use their devices, and machines and data can be **adjusted to an individual's health history**.
- Both **specific hormone** and **fertility tracking summary** data can be reported back to patients.

- Founded in **2024** from similar research done at the **California Institute of Technology.**
- Received **$1 million dollars** in **pre-seeding** funding an and additional **$3 million dollars** in a partnership with **ARPA-H.**
- Run exclusively by researchers and post-doctoral researchers, many of whom **previously** or are **simultaneously** working on **other women's health research ventures.**

| | |
|---|---|
| **Data Interpretation** | Pateints are given real-time results from the **wireless transmission** between the wearable devices and a connected smart device. **Menstrual**, **ovulation**, and **specific hormone** (like estrogen) data is collected through the **analysis of sweat**, and results can encourage users to make their own health decisions or consult a physician. |
| **Non-Invasive Collection** | Traditional methods of data collection are often invasive and involve lab procedures- using external monitoring technology aims to **reduce concerns and barriers** that patients may have when **facing traditional methods of hormone monitoring**. Secure data storing software is also implemented to **ensure patient confidentiality**. |
| **Future Technology** | Because research is consistently done on the types of information that can be extracted from sweat analysis, **future developments** hope to capture insights about **chronic pain**, **mental health**, **early detection methods**, and stress management. Personalized results and more confident diagnoses may also be apart of the company's future plans. |
| **Company Mission** | **Specializations in fertility treatments** - with the tracking of ovulation and analyzing estrogen levels and it relevant to reproductive health – **and menopausal symptoms** – which may include temperature monitoring in the future, but currently assess hormones as compared to an individual's baseline – are also available through Persperity. |

### Key Takeaway

Perpserity continues to develop their **wearable technology capabilities** and **interpretation models** to improve the diagnosis and identification of **hormone imbalances** and changes in women.

*Folkendt*, *O'Sullivan*, *Persperity*

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# AI-Powered Diagnostics & At-Home Trackers

AI-powered diagnostics and at-home trackers are integrated into the products of the current FemTech market leaders, relying on various types of data to provide specific results. However, issues in reliability and credibility are still prominent.

## Market Overview

- Various FemTech startups utilize AI as a **key player** in providing **insights** on symptoms and diagnostics.
- Flo is an AI-powered period tracking app that recognizes **patterns** and **symptoms** customized to individual users.
- Oova utilizes an **at-home** urine **test** and AI-powered **smartphone** app to give results on hormone detection.
- Endometrix is an endometriosis **symptom-tracking app** that offers AI-powered **insights** into **results**.

## PROMINENT TRACKERS AND DIAGNOSTICS

Flo, Clue, OOVA, mira, ada, bloomlife

| Data Type | Examples of Data Collected |
|---|---|
| Self-reported | Daily pain **scores**, bleeding **pattern**, bowel or bladder **symptoms**, medication, activity, and mood (based off a **numerical scale**). |
| Passive or biometric (whenever available) | **Daily** steps or activity via **wearables**, HRV, and sleep **metrics**. |
| Biofluid markers | Hormone **levels** through urine **strips** (through at-**home testing**). |

| | |
|---|---|
| **Consumer Response** | • Apps like Clue and Flo have **millions** of downloads and **high** visibility, having **strong** feature scores in app evaluations and clinician endorsements.<br>• Oova has a **4.9-star** rating on its store page and **thousands** of paying users. |
| **Reliability** | • Perceptions depend on **transparency** of methods, third-party research **partnerships**, and clinical ties through **validation** and **accreditation**.<br>• At-home hormone testing reports **high** correlation with lab results in industry studies. |
| **Credibility** | • **Most** consumer trackers are not held to the **same** device-level **validation** standards as clinical assays or FDA-cleared diagnostics, creating a **regulatory loophole**.<br>• Provider **confirmation**, not FemTech app results, remains the **clinical standard.** |

*BMJOpen, Endometriosis, Nature, PubMed, Potter Clarkson*

# Case Study: Oova

Oova is a hormone-tracking and AI analytics product that provides insights for women about fertility, perimenopause, and irregular menstrual cycles. Its usage of AI for time-series data and computer vision contributes to its success.

OOVA

**Company Overview**

- Oova is a FemTech company who manufactures **AI-enabled** at-home hormone **testing** products.
- Its product analyzes at-home urine **testing strips** for hormone detection with an **AI** smartphone **app**.
- Oova gives users **convenient** and **detailed insights** into fertility, perimenopause, and irregular cycles.

**AI Implementation**

- Oova uses **computer vision** to scan and analyze images of testing strips and converts data through a model.
- **Predictive analytics** generate daily insights each day, which are displayed to users in the smartphone app.

**Company Validation**

- Oova's clinical validation has been recognized by **ASRM** (American Society for Reproductive Medicine), **ACOG** (American College of Obsetricians and Gynecologists) and The **Menopause** Society.
- Oova is marketed as **credible**, having a background of being developed by **Mt. Sinai physicians** and being recommended by over **400** healthcare providers.

**Limitations**

- **Algorithmic bias** arises as AI **models** are typically trained on **limited populations**, reducing accuracy.
- Press releases and company-sanctioned studies are **not viable evidence** for medical claims.
- Clinical and regulatory boundaries matter, and marketing products as "diagnostics" poses an **overclaiming risk.**

**Clinical and Consumer Response**

- Oova has **high** user ratings and over **several hundred** clinic integrations and partnerships under its belt.
- However, various literature reviews urge **caution** when integrating its technologies into **clinical practice**.

**Application of AI**

- Oova uses **time-series data** and **predictive analytics** to drive insights through its tracking functionality.
- This approach is also **effective** for illnesses like endometriosis, where symptom **tracking** and management is crucial to **diagnosis** and **prognosis**.

**Symptom tracking**

**Hormone Monitoring**

**Time-series Data**

*Mount Sinai, Oova (I), Oova (II), PubMed (I), PubMed (II)*

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# Technical, Ethical & Privacy Concerns in AI-Enabled FemTech

The rapid growth of AI-driven Women's Health and FemTech has amplified technical, ethical, and privacy challenges and revealed major gaps in transparency, data protection, and user trust across the global digital health industry.

**60%**

of Americans say they would **feel uncomfortable with providers relying on AI** in their own health care.

**80%**

of popular period- and pregnancy-tracking apps **share their users' data with third parties** such as advertising and analytics companies.

**92%**

of people believe **privacy is a right** and **their health data should not be available for purchase** by corporations or other individuals.

| | |
|---|---|
| **Ethical and Societal Concerns** | • Large-scale user bases (~70 million Mean Annual Users) mean that **any bias in cycles, fertility, symptom-data models can affect millions**.<br>• Considering that **84% of apps share sensitive health data with third parties**, women from marginalized groups risk **disproportionate exposure** and misuse. |
| **Operational Best Practices** | • In a study of 796 M health apps, **23.7% lacked a complete privacy policy**, 59 apps **collected sensitive data**, and 77.9% contained **inconsistent collection** behaviors.<br>• Many FemTech apps **share sensitive health data** with third-parties **without on-device processing** (only 1 in 25 apps kept all sensitive data on device). |
| **Product & Service Quality** | • Under **Europe's GDPR**, reproductive health data qualify as **"special category"** data, with more restrictions, but many consumer apps **fall outside HIPAA's protections**.<br>• Global women's health app market estimated at **$4.85 B** in 2024 and projected to reach **$12.87 B by 2030**; large market means high stakes for compliance. |
| **Technology & Infrastructure** | • Apps with **tens of millions of users** create the added danger that any **data breach** or **misuse** can negatively affect large populations.<br>• Public reporting shows **user trust is fragile**: only **34% of consumers say companies are clear about how they use data**; women tend to be more skeptical. |

**Key Takeaway**

With **84% of FemTech apps sharing sensitive data**, the industry's projected **billion-dollar growth by 2030** depends on implementing **transparent AI models, on-device or federated data processing, and full GDPR-level compliance** to protect users' autonomy and safety.

*ARXIV, AMA, Deloitte, Duke, Fierce Healthcare, Grand View Research, ORCHA, Pew Research Center*

# Case Study: Clue

Through strong General Data Protection Regulation (GDRC) compliance, user consent controls, and public transparency reports, Clue has been a leader in how FemTech firms can operationalize ethical AI in sensitive health contexts.

### Company Overview

- Founded in 2013 in Berlin; among the **first FemTech companies to gain CE marking as a Class IIb medical device for contraception** in 2018.
- Serves over **10 million monthly active users across 190 countries** as of 2024.
- Uses **AI to predict ovulation and fertile windows** based on self-reported cycle data and **population-level pattern analysis**.
- Target audience: **women 18-45 seeking cycle tracking**, fertility awareness, and contraception without hormones.

### Privacy and Ethical Management

- **GDPR-compliant** by design: servers hosted in Germany; **no data sold or shared for advertising**.
- Explicit user consent required for data analytics; **users can delete all records instantly**; **100% data-deletion compliance in 2023 audit**.
- 2022 Dobbs v. Jackson decision and **President Trump's re-election** → Clue publicly reaffirmed that **"no reproductive data will ever be shared with U.S. authorities."**
- Uses differential privacy and **aggregated modeling** → individuals' data **cannot be reverse-engineered**.

### Challenges & Transparency

- On Feb 18, 2021, **Clue's "Birth Control"** feature received **FDA 510(k) clearance** (K193330) as a software contraceptive device; from external reports, **92% typical-use & 97% perfect-use effectiveness** found.
- The app faced scrutiny in 2019 for accuracy claims; studies found **fertility prediction accuracy ≈ 65–75 percent**, depending on logging frequency.
- Clue publishes **annual transparency reports** detailing data access requests; **zero access was granted to law-enforcement in 2023**); maintaining public auditability is a priority.

## Key Takeaway

Key takeaway: FemTech companies must implement **on-device or federated learning**, ensure **quantified transparency** about data use, conduct **regular bias audits**, and provide **granular consent mechanisms** to build trust and accountability in AI-driven health technologies.

*Clue (I)*, *Clue (II)*, *EMA*, *FDA*, *Newsweek*

Market Research & Funding Landscape

Critical Analysis of Current Solutions

**Challenges & Bottlenecks**

Strategic Recommendations

# Challenges & Bottlenecks

Each challenge area poses a specific, critical bottleneck to implementation, and potential solutions rely on potential strategic partnerships, modeling of positive case study examples, and a larger societal conversation about gender gaps.

## Section 1: Unclear Health Regulations

Section 2: Financial Acquisitions & Disparities

Section 3: Societal & Ethical Concerns

# Impact of Unclear Health Regulations

Unclear health regulations in FemTech regulations compromises reliability, endangers user data, and encourages loopholes due to the lack of strict regulatory frameworks that moderate FemTech applications.

## Regulatory Overview

- FemTech products often fall between **wellness tools** and **medical devices**, depending on their intended use.
- Cycle-tracking apps may be considered **wellness**, but apps aiding fertility, contraception, and diagnosis all require **official** medical device **approval**.
- This gray area is the cause behind **delays**, added costs, and **inconsistent** FemTech market entry decisions.
- AI algorithms, data privacy, and digital health overlaps can also further **blur** classification **boundaries**.

## Current Gaps

- **Regulatory loopholes** are a major issue, as various FemTech companies will market applications under "**wellness**" to avoid **medical devices** regulations.
- **Limited clinical validation** due to most apps remaining **outside device regulation** poses risks.
- **Global variations** in device classifications can cause **confusions** over the regulations that apply.
- Robust frameworks are needed to **safeguard** the **highly sensitive health data** of users.

## Global Comparisons

| United States Food & Drug Administration (FDA) | United Kingdom (UK) | Japan |
|---|---|---|
| Devices are classified into classes I/II/III based on risk to patients. | Device must have a "medical purpose" to be certified. | FemTech devices must partner locally or adapt to local import and registration rules. |
| Softwares may be classified as a Medical Device (SaMD). | For software, there are official documents to help classification. | Guidelines for SaMD and evaluation indexes are slowly evolving and new. |

**Natural Cycles (US/EU)**

- Founded in 2013, Natural Cycles has **over five million registered users** and **over $100M raised from investors** including Samsung Ventures.
- The company developed the **first FDA-cleared digital birth control method** in the United States, while also getting **regulatory clearance** across Canada, Europe, Brazil, Australia, Singapore, and South Korea.

**Premom (US)**

- In May 2023, Premom, an American **fertility and ovulation-tracking app**, paid $200K USD to settle claims that it shared sensitive user data with third parties after **failed data encryption.**
- Premom is an example of the data security concerns surrounding FemTech apps and highlights the importance of the regulatory frameworks in ensuring the safety of patient data and privacy.

**Fertility Tracking Apps (UK/EU)**

- A 2022 literature review found that many UK-based fertility and menstrual tracking apps **escape device regulation** as they claim to only **log or display data**, not treat or diagnose conditions.
- Many users still rely on FemTech apps for conception and contraception decisions despite the lack of device regulation and clinical approval, raising concerns about reliability of FemTech.

*BCL Law*, *Consonance Tech*, *Edinburgh Law School*, *English Kyodo News*, *FemTech Insider*, *FemTech World*, *Morton Fraser Macroberts*

# Bottleneck: Health Regulations

The "Classification" Gap in health regulation for FemTech applications has led to various issues with user privacy and regulatory loopholes, but solutions aimed at creating more tailored regulatory pathways help mitigate current challenges.

## Specific Bottleneck: "Classification" Gap

- There is **no single legal or regulatory framework** governing FemTech design, use, and marketing due to **varied nature** of FemTech applications, from medical devices to tracking apps.
- Global pathways for regulation require **separate strategies** and often **reclassification**, inflating time and costs when FemTech applications attempt global scale leading to **regulatory loopholes**.
- Many apps collect **sensitive reproductive data**, and **lack of tailored regulation** leaves users exposed to **data privacy, clinical accuracy, and safety risks** coming from unregulated apps.

## Case Study: Flo

- Flo is a global period and fertility tracking app which is marketed as a wellness and lifestyle product rather than a medical device.
- Flo was investigated by the U.S. FTC in 2021 for **sharing sensitive reproductive data** with third parties **despite privacy assurance**.
- The classification gap allows for apps to **avoid device-level regulations**, leaving vulnerabilities unaddressed.

## Solution 1: Subcategorization of FemTech Products

- Global regulatory agencies can create **specific sub-classifications** for "Digital Health Adjacent" or "Preventive Health" products.
- **Risk tiers** can be based on intended use, data collected, and impact on health decisions.

## Solution 2: Regulatory "Sandboxes"

- Sandbox programs allow startups to test products under **real-world conditions** and **direct regulatory oversight**.
- This spurs **collaboration** of startups, clinicians, and regulators to refine classification guidelines in real-time.

## Case Study: Natural Cycles

- Natural Cycles was the first app to receive clearances as a FDA Class II contraceptive device in 2018.
- Its regulatory journey demonstrates that digital health products can achieve **medical device classification**, but approval timelines are **costly and extensive**.
- This shows how **requirements can discourage** smaller FemTech firms from pursuing regulatory pathways.

## Solution 3: Harmonize International Regulations

- International coalitions can **align definitions** for FemTech medical devices and software.
- Strategies that support **mutual recognition agreements** will help **standardize evaluation criteria** for digital health risk assessments.

## Solution 4: Adaptive Regulatory Pathways

- **Post-market surveillance** is a new form of regulation that adapts to the fast-growing AI applications available in FemTech markets.
- Enforcing **continuous performance reporting** and **safety updates** ensures transparency for users, balancing innovation with safety.

### Key Takeaway

The **gap in classification** has led to issues where patient data and safety have been compromised, however, solutions aimed toward providing a **more tailored regulatory framework** can address current issues.

*BCL Law*, *Edinburgh Law*, *ETH Zurich*, *Frontiers*, *Morton Fraser Macroberts*, *Paragon Institute*

# Challenges & Bottlenecks

Each challenge area poses a specific, critical bottleneck to implementation, and potential solutions rely on potential strategic partnerships, modeling of positive case study examples, and a larger societal conversation about gender gaps.

Section 1: Unclear Health Regulations

**Section 2: Financial Acquisitions & Disparities**

Section 3: Societal & Ethical Concerns

# Impact of Financial Acquisition & Disparities

Many barriers exist for women to access FemTech and for FemTech companies to arise, with a root cause being a lack of education and previous, historical research that is able to be cited in support of women's health issues.

## Privacy Concerns

Some investors are hesitant to lean into FemTech investments because of a lack of focus on **user privacy and technological safeguards** to ensure that data is not leaked. The need for technological and legal expertise may cause investors to hesitate with funding.

## Insurance Issues

Insurance is less likely to invest in women's health because of a **lack of historical research**, broker and underwriter complications, **pre-written exclusions** about "experimental" healthcare, or **outdated insurance policies** that did not include women's health.

## Lack of Regulation

Companies that reach global scale face the issue of **different legal standard** for healthcare and data reporting, which may arise a need for **more human and capital resources** in a region. Investors may be unwilling to invest in a company that has diverse funding needs.

## Lack of Education

Women's healthcare is often labelled as reproductive or menstrual wellness, when an estimated **43% of the diagnosis gap** is caused by **general ailments** that affect women disproportionately, but some "FemTech" companies decide to cater to an all-gender audience.

## Key Takeaway

Investors may be weary of the problems faces by FemTech companies in the past and the broader issues that currently face FemTech as new technological advancements are made and subsequently regulated.

*arXiv*, *BMC Medical Ethics*, *Insurance Business Magazine*, *McKinsey (I)*, *McKinsey (II)*, *McKinsey Health Institute*, *MFMac*, *University of Michigan*

# Bottleneck: Financial Acquisition & Disparities

A bottleneck around funding exists with the perceptions of the market from predominant market investors, which are predominantly male, leading to lack of monetary and human resources, further disadvantaging FemTech companies.

## Predominantly Male Investors

- Male FemTech startups raise **9.2 million dollars** on average, and women-founded startups raise **4.6 million dollars** on average (despite 70% of startups being founded by women)
- Despite there being more female investors, there are fewer general partners (89% male) that are able to provide large enough sums to fully fund a project.
- Only **2.4% of venture capital** goes towards startups **founded by women.**

## Oversaturation

- There is a perception that FemTech is **an oversaturated market**, namely among key investors, which may dissuade an investor from a FemTech startup.
- A gap also exists in **communities of color and queer communities** that leads to **less availability** within those communities, but more startup that overlap in the demographic they market their product or service towards.

## Employment Differences

- FemTech tends to attract **individuals with less experience**, meaning that employees are **often paid less** and **are perceived as "unskilled labor."**
- Though **60% of founders are women**, **only 12% of successful startup boards are females**, with only 0.67% of those positions being non-white.

*All Rise*, *Crunchbase*, *Deloitte*, *Forbes*, *HBR*, *McKinsey*, *Pitchbook*, *TechCrunch*

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# Impact of Societal & Ethical Concerns

Persistent stigma, inequitable access, privacy concerns, and clinical skepticism hinder FemTech's normalization, with privacy lapses and limited inclusivity deepening distrust among users and providers and limiting widespread integration.

## Social & Cultural

### Silence Around the Stigma

**Stigma** around **menstruation**, **fertility**, and **menopause discourages open discussion** and hinders FemTech's normalization as part of mainstream care; a Thinx/Harris Poll found **62% of U.S. teens** believe **society teaches people to be ashamed of periods** + **74% admit to downplaying how they feel** to not be "dramatic."

### Fear of Data Misuse

**Data privacy** remains a major barrier to user trust, especially following incidents like the **FTC's 2021 case against Flo Health for sharing sensitive reproductive data with analytics firms**. Concerns over **surveillance**, **data resale**, and **breaches** make users hesitant to adopt technologies that collect intimate health information.

### Unequal Access Across Demographics

Adoption patterns reveal severe **inequities across age**, **region**, and **income level**. In **low-and middle-income countries**, women remain **14% less likely than men to own smartphones**, which restricts access to mobile-based health technologies and exacerbates the **digital divide** that keeps FemTech **out of reach for millions**.

## Clinical & Systematic

### Lack of Clinical Validation

Some FemTech products face **skepticism due to limited clinical validation** + **weak regulatory oversight**. Despite few exceptions (**Natural Cycles** secured **FDA clearance** from **testing 15,570 women**), most products seen as **wellness tools** rather than credible medical devices, **eroding clinician confidence**.

### Clinician Hesitation and Workflow Gaps

Clinicians' hesitancy to endorse FemTech stems from **limited integration into care systems**, **uncertain clinical value**, and **workflow disruption**. Studies show physicians need **clear evidence**, **data security**, and **EHR compliance** before recommending digital tools; **lack of institutional trust** directly **slows broader adoption**.

### Narrow Scope and Limited Trust

**Limited inclusivity** + **unclear outcome data alienate stakeholders**. Many products **underrepresent trans, non-binary, and older women** + healthcare systems **hesitate to** integrate apps without solid **ROI evidence** (seen with **Maven Clinic's** maternity program, which reports gains yet remains viewed **as niche > systemic**.

*FTC*, *Girls Helping Girls Period*, *GSMA*, *Healio*, *Maven*

# Bottleneck: Societal & Ethical Concerns

By addressing widespread fears of data misuse through transparent privacy practices, opt-in data sharing, and user-controlled dashboards, FemTech companies can generate trust, compliance, and sustainable competitive advantage.

| Steps | Criteria/Details |
|---|---|
| 1 **Privacy Concerns as a Social Barrier to FemTech Adoption** | • **Over 50% of women hesitate to use FemTech apps due to fears of data misuse**, particularly regarding menstrual or fertility information post-Dobbs v. Jackson ruling and privacy uncertainties.<br>• A 2024 BMJ Global Health audit of the top 20 FemTech apps found **more than 60 % shared personal health data with analytics or advertising firms without explicit user consent or disclosure**.<br>• **Privacy breaches expose users to legal or social harm → builds fear among platform users** that their data in "the wrong hands" could lead to **job discrimination, insurance bias, or limited abortion access**. |
| 2 **Case Study Solutions: Reframing Privacy as a Trust-Building Tool** | • After a 2021 FTC investigation for sharing data with Facebook & Google, **Flo launched "Anonymous Mode" (2022), allowing users to access features without personal identifiers**. Adoption surged, leading Flo to reach 380M downloads and 70M monthly users in 2024, successfully reframing privacy as a **brand differentiator**.<br>• **Clue** is one of the first period-tracking apps to publish **transparent privacy reports** detailing how **no data is sold/shared with advertisers** (full GDPR compliance). Following 2023 privacy-transparency campaign, Clue's **active-user base increased by 22% year-over-year** (competitive advantage). |
| 3 **Trust & Transparency as Competitive Advantages** | • Because **trust is key driver of digital health adoption** (users 6× more likely to stay if they trust the provider), FemTech firms should build **opt-in models** and **visible, user-controlled dashboards** around data use.<br>• With **documented risks in women's health apps** (35% misstated third-party sharing), the industry should **adopt independent audits of data-sharing** to become a competitive differentiator as regulation rises.<br>• Using **metrics like "% opting into data-sharing," "retention vs trust-score," and "incidence of sharing complaints" to monitor impact**; draws in investors by demonstrating that privacy investments drive growth. |

*Deloitte, FemTech World, Flo, Privacy International, Team Lewis, Texas A&M*

Market Research & Funding Landscape

Critical Analysis of Current Solutions

Challenges & Bottlenecks

**Strategic Recommendations**

# Strategic Recommendations

This section summarizes strategic considerations for a startup attempting to enter the FemTech market and larger market concerns. It also provides specific development/implementation notes which outline the process of turning these recommendations into feasible solutions.

# Recommendations for FemTech Startups

With increased engagement towards women's health innovations, FemTech has a positive outlook, but challenges with funding acquisition and representation require strategies that strengthen startup narratives and target current trends.

## Strategic Recommendations

### Build Investor-Ready Narratives

Given the difficulty of female-founded startups in a male-dominated healthtech VC atmosphere, FemTech startups should **craft compelling** and **sound narratives** around their products. Seeking **clinical validation early on**, **complying with government regulations**, acquiring **female talent**, and **sourcing pilot groups** will give a startup unique identity. Maintain clear implementation, detailed hiring frameworks, and on-the-ground connections.

### Prioritize Digital-First Promotion

Especially with the large relevance of AI products with Gen Z and Millennial populations, FemTech startups should **prioritize digital marketing** through content creation and social media presence. Building **digital-native products**, integrating **asynchronous features** to stay updated, and **integrating pilot groups for feedback**, will allow startups to flourish. Ensure data privacy, clinical validation, and credibility is maintained.

## Key Takeaway

FemTech provides a **major market of growth** due to the novel use of AI in disease diagnosis, prognosis and symptom management for **female-focused chronic health conditions**. While market outlook is favorable, issues surrounding representation of founders, funding acquisition, and limited visibility are prominent struggles. Through taking advantage of **digital resources** and **strengthening brand narratives**, FemTech startups can accurately address these challenges for successful growth.

*Harvard Business School*, *Innovation Magazine*, *Seedtable*, *Vestbee*

## FemTech Startup Market Status Quo

### Positive Outlook and Digital Innovation

- The FemTech market provides massive opportunity as stigma towards women's health decreases and **digital, online, and AI products** increases in relevance with younger populations like Millennials and Generation-Z.
- Between 2014 to 2025, the **amount of ventures** in the FemTech market grew by **3.2 times**, signifying **large potential** for future products.
- Current **highest-valued sectors** for FemTech applications surround **chronic diseases**, with products intended to help diagnose, manage, and track symptoms of endometriosis, ovarian cancer, and polycystic ovary syndrome.
- **Government support**, such as investments from the White House, can drive further market development and fund breakthrough research.

### Challenges with Representation and Venture Capital

- While most FemTech startups are founded by women, the **funding raised by men is almost double** that of the funding raised by female founders.
- FemTech represents a **small fraction of the portfolios of generalist VCs**, as well as only a small portion of U.S. healthcare VC funding as well.
- Women-backed health funds are **rare and have limited capital**, but still exist, investing in menopause, reproductive and sexual health related ventures.
- With a majority of men applying to work in startups, most men are not inclined to apply for a female-backed venture, such as FemTech.

# Recommendations for Partnership Pathways

By combining clinical validation with consumer-facing co-branding initiatives, FemTech startups can build trust, attract investors, and reach broader audiences more effectively, driving long-term innovation and sustained growth.

| | Validation Partnership with Academic or Clinical Research Institution | Co-Branding Partnership with Consumer Health or Beauty Brand |
|---|---|---|
| Description & Rationale | **Description:** Seek **collaboration with academic or clinical institutions** to validate product efficacy, usability, and safety through **peer-reviewed formal studies** and applicable, **real-world trials**.<br><br>**Rationale:** Builds strong evidence-based **credibility**, **accelerates FDA/CE approval** processes, and boosts **investor/clinician confidence**. Aligns with **growing market demand** for verified, data-driven FemTech solutions **supported by independent research**. | **Description:** Partner with **trusted consumer health or beauty brands** to co-create **campaigns** + **smart wellness products** that integrate FemTech with lifestyle appeal → promotes accessibility + mainstream awareness.<br><br>**Rationale:** Expands **market visibility**, **normalizes conversations** around women's health, and **attracts new audiences** through trusted channels. **Aligns with demand for inclusive, empowering, and science-backed wellness solutions** in both the global FemTech and beauty spaces. |
| Implementation & Considerations | **Implementation:** 1) Identify **institutions aligned with product focus** (e.g., reproductive health, mental wellness). 2) Draft research agreement outlining **data use**, **IP rights**, study scope. 3) Conduct small-scale validation study → **scale to larger trials**.<br><br>**Considerations:** 1) Long study timelines, potential **funding needs**. 2) Requires **IRB approval** and **strict data governance**. 3) Balance academic rigor with startup agility. | **Implementation:** 1) Identify brands aligned with **target demographics and shared wellness values**. 2) Develop co-branded visuals, packaging, and messaging reflecting both identities. 3) Launch joint awareness campaigns with **measurable engagement and sales outcomes**.<br><br>**Considerations:** 1) Accuracy of brand messaging. 2) Management of potential **conflict between commercial/clinical priorities**. 3) Maintain **authenticity** and trust by **accurately representing** women's health issues. |

*Business Wise, European Symposium on Useable Security, McKinsey, ZS*