elle

Strategy Summary

The problem

The challenge of women's health in Africa transcends mere access to sanitary products and contraceptives; it's a multifaceted issue intertwined with cultural stigma, limited resources, and educational gaps. Many women and girls face insurmountable obstacles in managing their health due to the unavailability of affordable, sustainable, and safe hygienic products, diagnostics, and treatments. This scarcity not only impacts their physical well-being but also deters their educational pursuits and economic participation.

Throughout the region, women's health remains a taboo subject, leading to widespread misinformation, shame, and exclusion. Coupled with limited access to proper facilities and resources, girls frequently miss school during their menstrual cycles, perpetuating educational disparities hindering their overall development.

Across Sub-Saharan Africa health burdens for women are systematically underestimated, with an absence of data that exclude or undervalue important conditions. Women face barriers to care, diagnosis, and suboptimal treatment. In addition, there has been lower investment in women's health conditions relative to their prevalence, reinforcing a cycle of weaker scientific understanding about women's bodies and limited data to de-risk new investment.

Elle International's efforts are therefore substantially more than providing sustainable menstrual products; it's about recognising the problem in the context of women's health, fostering an environment where menstrual and reproductive health is normalised, integrated into societal discourse, and women are provided with the care they need. Through this holistic approach, we catalyse positive social change, uplift communities, and contribute to gender equality and women's empowerment in Africa.

The context in South Africa

~ 7.7 million girls and women in South Africa don't have the financial means to purchase sanitary products.

~ 10% of women live with endometriosis.

 ~ 11-year average diagnostic delay for endometriosis.

~ 90% women experience menstrual pain and cramping around their period.

~ 7 million girls miss 25% of their schooling each month due to:

1. Lack of pre-menarcheal training.

2. Lack of access to safe and sustainable menstrual products.

3. Lack of dispensing of pain medication (NSAID's) for pain management.

4. Lack of access to medical professionals to deal with their unique needs during their reproductive journey.

5. Lack of diagnosis for menstrual and reproductive disorders.

6. Lack of research data to drive diagnostics, treatments, and cures.

7. Lack of data to provision AI enabled healthcare services.

8. Lack of assurance in the provision of products and services.
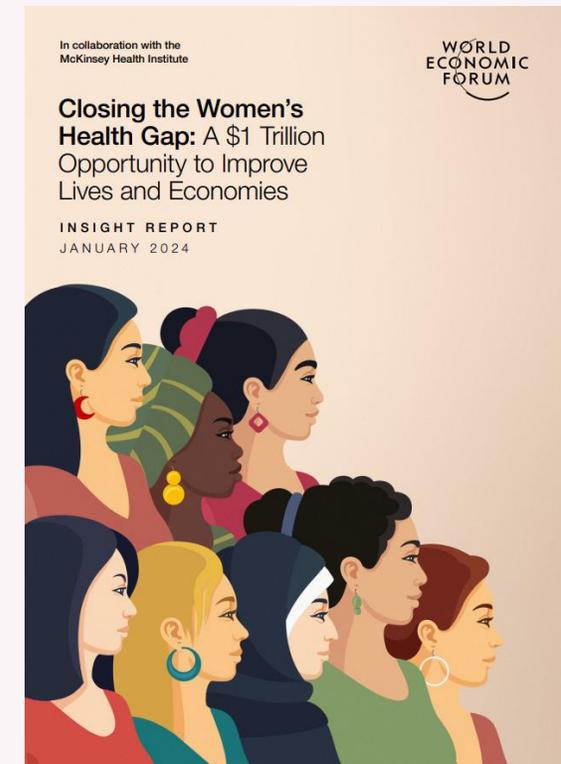
Elle's context driven solution

1. Lack of pre-menarcheal training.
    - **Education programmes**

2. Lack of access to safe and sustainable menstrual products.
    - **Elle menstrual product line**

3. Lack of dispensing of pain medication (NSAID's) for pain management.
    - **Moxie**

4. Lack of access to medical professionals to deal with their unique needs during their menstrual journey.
    - **Womany**

5. Lack of diagnosis for menstrual disorders.
    - **Elle diagnostics**

6. Lack of research data to drive diagnostics, treatments, and cures.
    - **ElleStudies**

7. Lack of data to provision AI enabled healthcare services.
    - **ElleHealth**

8. Lack of assurance in the provision of menstrual health products and services.
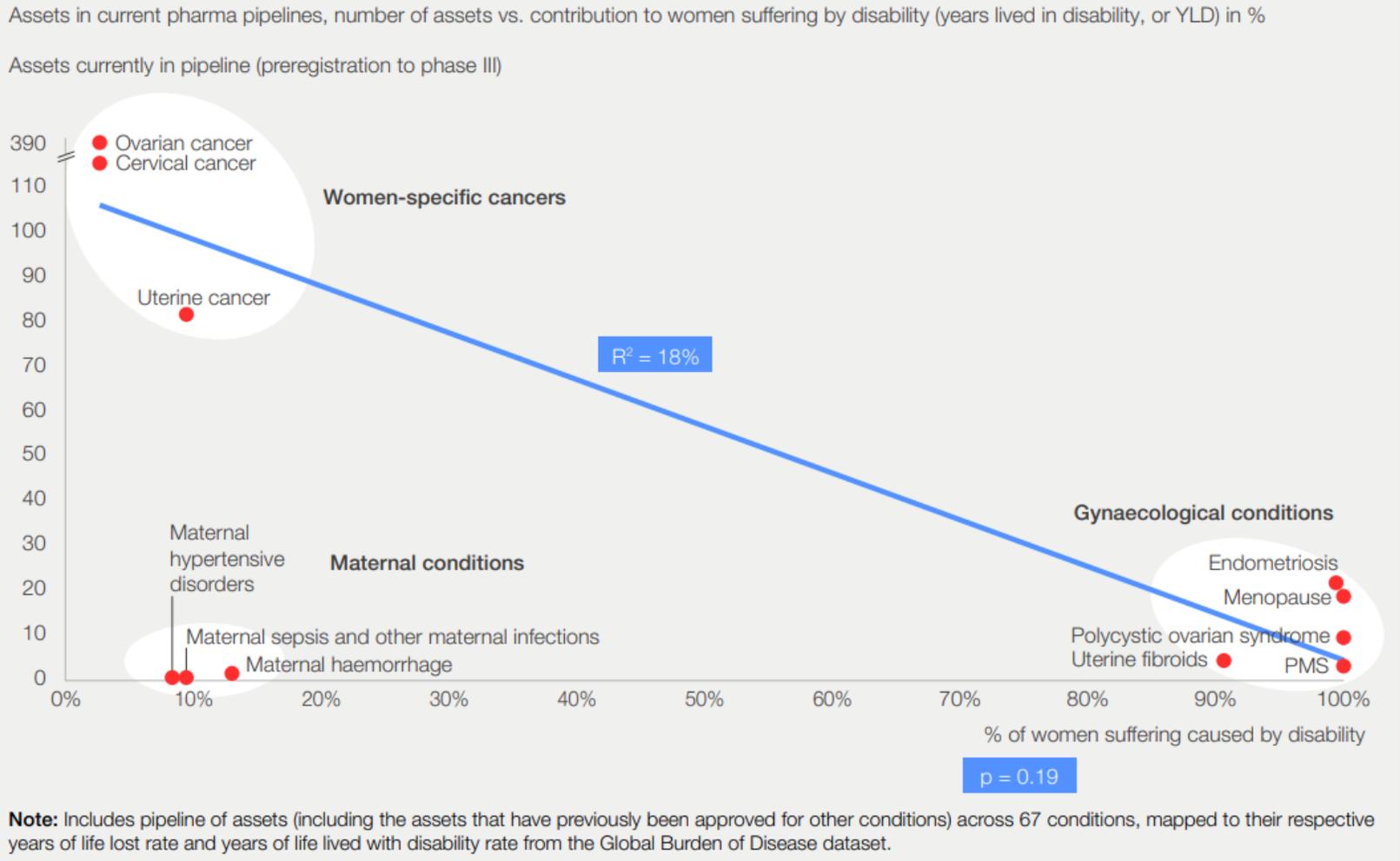   - **Moxie** and **assurance driven products and services**

The women's health gap

Narrowing of the women's health gap would allow 3.9 billion women to live healthier, higher-quality lives. It could also allow at least **$1 trillion annually by 2040** to be pumped into economic productivity, which reflects how narrowing the gap would lead to fewer early deaths, fewer health conditions, extended economic and societal capacity to contribute, and increased productivity.

These estimates – while significant – are likely an underestimation given data limitations.

In collaboration with the
McKinsey Health Institute

WORLD
ECONOMIC
FORUM

Closing the Women's Health Gap: A $1 Trillion Opportunity to Improve Lives and Economies

INSIGHT REPORT
JANUARY 2024

The women's health gap

Assets in current pharma pipelines, number of assets vs. contribution to women suffering by disability (years lived in disability, or YLD) in %

Assets currently in pipeline (preregistration to phase III)

Women-specific cancers
- Ovarian cancer
- Cervical cancer
- Uterine cancer

$R^2 = 18\%$

Gynaecological conditions
- Endometriosis
- Menopause
- Polycystic ovarian syndrome
- Uterine fibroids
- PMS

Maternal conditions
- Maternal hypertensive disorders
- Maternal sepsis and other maternal infections
- Maternal haemorrhage

% of women suffering caused by disability

$p = 0.19$

Note: Includes pipeline of assets (including the assets that have previously been approved for other conditions) across 67 conditions, mapped to their respective years of life lost rate and years of life lived with disability rate from the Global Burden of Disease dataset.

[1] University of Washington
[2] McKinsey

Prevalence and diagnosis of women's health conditions

With less access to healthcare, women in Sub-Saharan Africa have few options for diagnosis of conditions.

Ratio of prevalence to diagnosis based on epidemiological data sources and US claims data (Jan 2019–Aug 2022)

● Estimated cases diagnosed
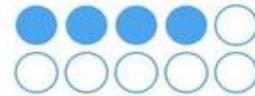○ Estimated cases not diagnosed

Women's health conditions

Menopause[1]
8 in 10 women are not diagnosed
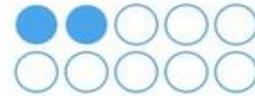
Endometriosis[2]
6 in 10 women are not diagnosed

PCOS[3]
2 in 10 women are not diagnosed

[1]Estimated US female population experiencing vasomotor symptoms; Craig Best et al., "Prevalence of menopausal symptoms in mid-life women: Findings from electronic medical records," *BMC Women's Health*, August 2015, Volume 15.
[2]"Endometriosis," Office on Women's Health, US Department of Health & Human Services.
[3]Polycystic ovary syndrome; Institute for Health Metrics Evaluation, used with permission.
[4]Arthur L. Burnett et al., "Prevalence and risk factors for erectile dysfunction in the US," *American Journal of Medicine*, February 2007, Volume 120, Number 2.
[5]Benign prostatic hyperplasia with lower urinary tract symptoms; Gary Boas, "Prostatic Artery Embolization (PAE)," *Radiology Rounds*, Massachusetts General Hospital Department of Radiology, September 2019, Volume 17, Number 9.
Source: © 2023 Komodo Health, Inc. All rights reserved. Reproduction, distribution, transmission, or publication is prohibited. Reprinted with permission; *American Journal of Medicine*; *BMC Women's Health*; Institute for Health Metrics Evaluation, used with permission; Massachusetts General Hospital Department of Radiology; Office on Women's Health in the Office of the Assistant Secretary for Health

McKinsey

Polycystic Ovary Syndrome (PCOS)

Diagnostics are nontrivial, but possible.

Variable	National Institutes of Health	Rotterdam	Androgen excess and PCOS society
Hyperandrogenism[a]	+		+
Ovulatory dysfunction[b]	+		
Polycystic ovarian morphological features[c]	–	≥2 of 3 criteria	≥1 of 2 criteria

Table derived from McCartney et al.[8]

a	Clinical (hirsutism assessed by the Ferriman–Gallwey scale, acne, and male-pattern hair loss) or biochemical hyperandrogenism (total and/or free testosterone, androstenedione, and/or DHEA-S level above the upper 95th percentile of 98 healthy non-hirsute eumenorrheic women).
b	Menses are interval <21 days or >35 days or eumenorrhea with progesterone <3 to 4 ng/mL a week before anticipated menses (days 21 or 22).
c	Polycystic ovarian morphological features are defined as 12 or more antral follicles (2–9 mm in diameter) in either ovary, an ovarian volume that is >10 mL in one or both ovary.

PCOS, polycystic ovary syndrome.

Women's health research and market

Research

A $300 million USD investment in women's health research could generate **$13 billion USD** in economic returns.

The Wham Report

Market

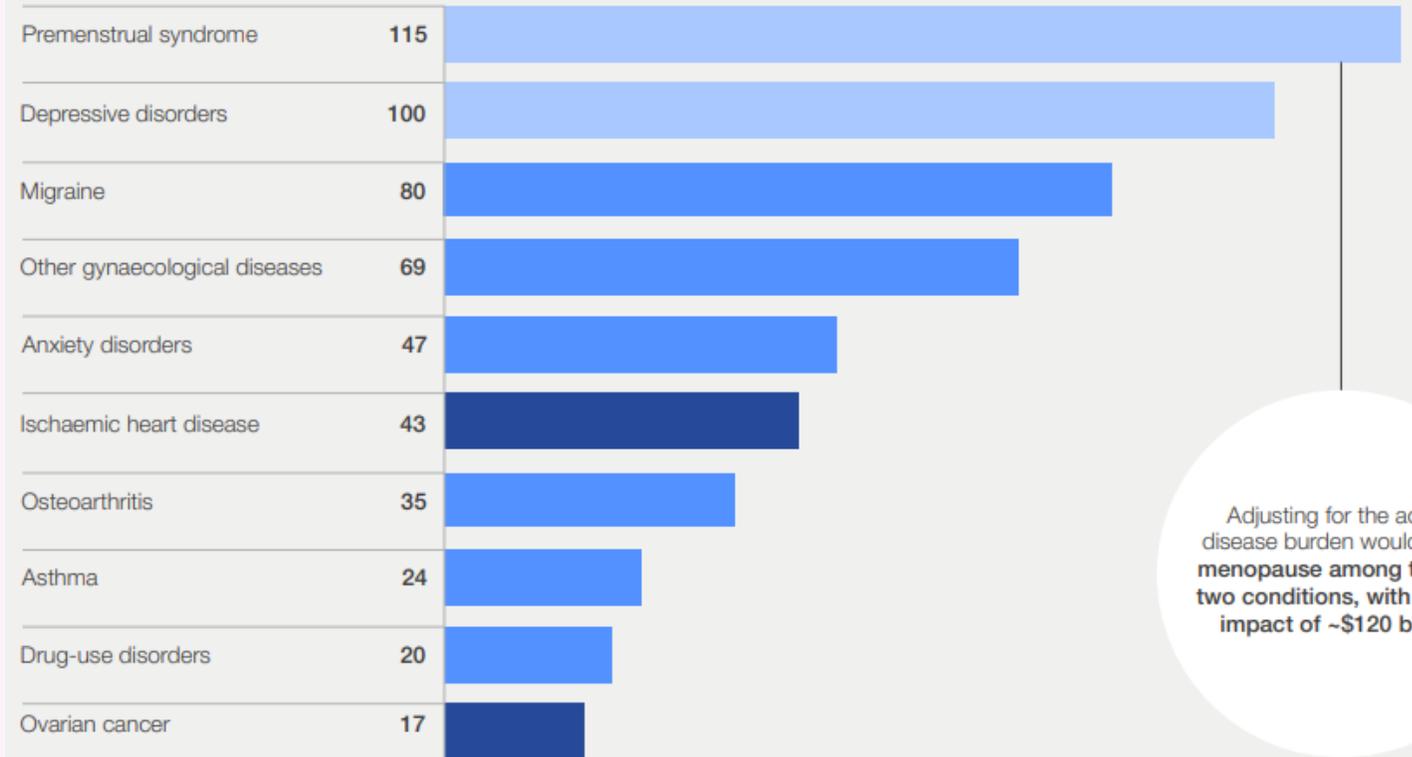By 2030, the women's health market could range from **$97 billion USD** to upwards of **$1.2 trillion USD**.

Women's Health Innovation Opportunity Map

Menopause

Approximately **80 percent** of women indicate that menopause interferes with their lives, and roughly one-third of these women also experience depression.

GDP impact of closing the women's health gap for the top 10 conditions, $ billions

Channel with the highest contribution to GDP impact: ● Fewer early deaths ● Fewer health conditions ● Increase in productivity

Condition	Value
Premenstrual syndrome	115
Depressive disorders	100
Migraine	80
Other gynaecological diseases	69
Anxiety disorders	47
Ischaemic heart disease	43
Osteoarthritis	35
Asthma	24
Drug-use disorders	20
Ovarian cancer	17

Adjusting for the actual disease burden would place **menopause among the top two conditions, with a GDP impact of ~$120 billion**

Note: Based on estimate, number of women aged 45–55 (excluding peri- and postmenopausal women), multiplied by the share of symptomatic cases (92%).

Source: Endometriosis prevalence from WHO; prevalence base for GDP impact calculation from IHME GBD (2019)

Fibroids

- Leiomyoma (fibroids) are common, present in **70% to 80%** of women by the age of 50 years.

  Menstruation: science and society - PubMed (nih.gov)

- Uterine fibroid tumours were estimated to cost the United States **$5.9 - 34.4 billion USD** annually.

  The estimated annual cost of uterine leiomyomata in the United States - ScienceDirect

Structural Causes "PALM"

Polyp
Adenomyosis
Leiomyoma
Malignancy

Non-Structural Causes "COEIN"

Coagulopathy
Ovulatory
Endometrial
Iatrogenic
Not Otherwise Classified (eg, AVM)

Critchley. Menstruation: science and society. Am J Obstet Gynecol 2020.
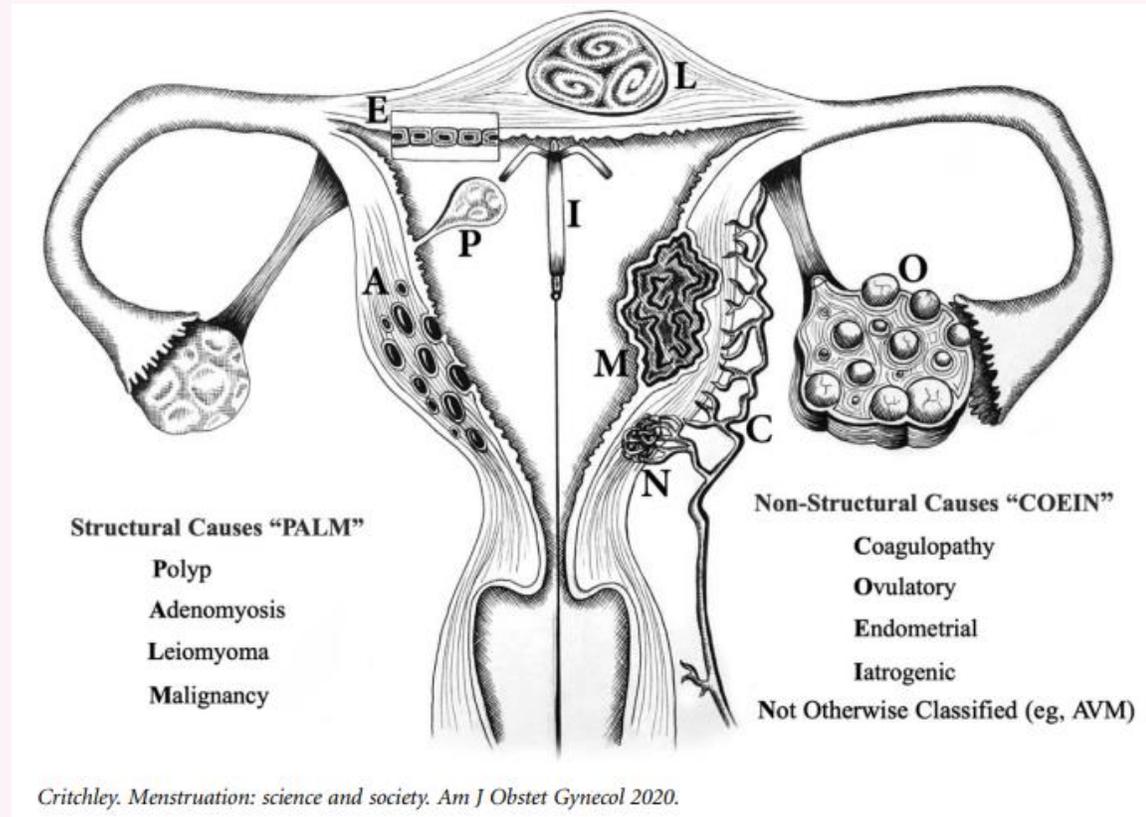
Mission statement

Elle International advances access to safe, sustainable, and affordable solutions for women's health, while empowering women through education and socio-economic inclusion.

What we do

CAMPAIGNS & PUBLIC ENGAGEMENT drive transformative, equity-based public policies and just socio-economic conditions for women and girls.

PROGRAMMES destigmatise women's health, impart accurate health information including pathways to care from prevention to diagnosis and treatment, empowering women and girls to make informed choices about their bodies and futures.

PERIOD CARE TO COMMUNITIES provide a sustainable and dignified way for women and girls to manage their periods.

DIGITAL PLATFORMS empower women and girls with agency over their health information, advance inclusive research, and provision equitable health services.

DIAGNOSTICS to overcome delays in diagnosis improving the quality of life for women and girls, reducing barriers to care, and prioritising needs for investors and researchers.

RESEARCH to democratise exceptional care and the research process to accelerate effective diagnostics, treatments, and cures for chronic diseases and disorders.

TREATMENTS that are evidenced based and patient centric in women's health.

PRODUCTS of the highest quality, safe, sustainable, affordable and accessible.

Catalysing Impact

Sustainable cities and communities

Right to health

Right to water and sanitation

Right to education

Improving quality of life through diagnosis of chronic diseases and conditions

Unified patient information for AI enabled healthcare services

Community leaders

Policy makers

Healthcare and implementation partners

Public commitment driven by an accurate understanding of menstrual and reproductive health

Transformed societal structures bridging the gap in women's health and empowering women and girls through promoting dignity, education, health, and socio-economic inclusion

Programmes

Period care to communities

Diagnostics

Campaigns & Public engagement

Treatments

NGO's

Affordability, and access to safe and sustainable products

Right to gender equality

Digital platforms

Products

Research

Schools

Right to human dignity

Media

Private sector

Democratise care and the research process to accelerate diagnostics, treatments, and cures

Right to work

What we do

Responsible consumption and production

Partnering with

Ending period poverty with period care

What we change

The world we build

Technological Ecosystem

1. Nonwoven organic plant-based fibres

- Latest generation manufacturing technology for efficiency, quality, and high output, including predictive maintenance.
- AI driven quality assurance.
- AI enabled data driven supplier assurance.

2. Product line

- Latest generation manufacturing technology.
- Diagnostic enabled products.
- AI enabled data driven supplier assurance.
- Engagement on education, research, and accessing products.

3. Moxie

- Location services for women to locate Moxie dispensers.
- NFC for product access and unifying physical products with Womany.
- Connectivity for stock and dispenser optimisation.

4. ElleHealth

- Enables the collection of comprehensive patient data, while preserving privacy, ensuring security, and placing the patient in full control.
- Patients themselves contribute directly to health information.
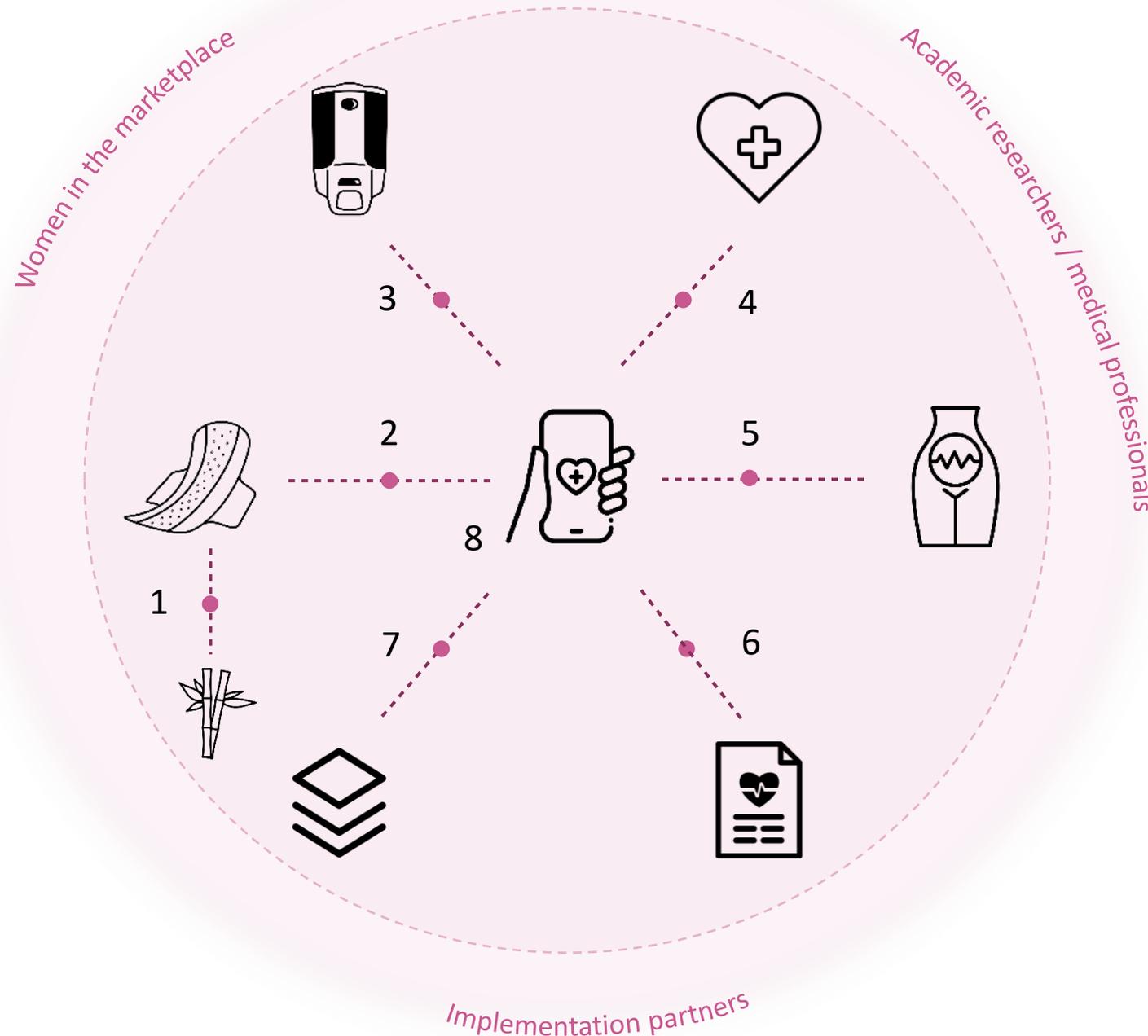
5. Diagnostics

- AI driven precision diagnostics commencing with menstrual and reproductive health, then maternal health followed by other areas of women's health.
- Includes AI inference on embedded devices for low resource environments.

6. ElleStudies

- The collection of good quality healthcare data, in a trusted and safe way.
- Revolutionise the management and tracking of women's health disorders, and other chronic diseases.
- Enables stakeholders to communicate traversing silos to share learning and enhance collaboration across initiatives to improve collective effort.
- Connects patients to verified information on best care practices, medical professionals, clinical trials, and similar patients near them to create community.

7. Data management platform

- Architected to support data ingestion and data management to store, manage, share, find and use data for AI enablement.

8. Womany

- Connects girls and women to verified information on best care practices and medical professionals to guide them on their health journey.
- Provides assurance for products and services.

Women in the marketplace

Academic researchers / medical professionals

Implementation partners

3   4
2   5
8
1
7   6

Elle's structure

Elle is comprised of **commercial** and **non-commercial** operations, with revenue from commercial activities supporting non-commercial operations.

Commercial

- Menstrual care
- Dispensers
- Treatments
- Diagnostics
- Partner products

Public Benefit Organisation

- Education programmes
- CSI programmes
- Corporate programmes
- Digital platforms
  - Womany
  - ElleHealth
  - ElleStudies

🏛 CAMPAIGNS & PUBLIC ENGAGEMENT

Policy
- **Prioritisation** – Ensuring women's health is prioritised.
- **Breadth** – Elucidating the breadth of women's health.
- **Collaboration** – Platform to share learning and enhance collaboration.

Health
- **Beyond hygiene** – A health and human rights issue.

Information
- **Expand information and knowledge** – To eliminate unsafe practices.
- **Awareness** – Safeguarding women's dignity to create an enabling environment.

Education
- **Curricula** – To reduce stigma and contribute to better education and health outcomes.

Product & Services
- **Equity enabled** – To support users in accessing their choice of products, services, diagnostics, and treatments.
- **Climate focused** – Sustainable solutions with minimal environmental impact.
- **Business driven** – Provide solutions that meet demand long-term, and support R&D for diagnostics and treatments.
- **Standards** – Standards to ensure products and services are of the highest quality, effective, and safe.

UPLIFT A **WOMEN** AND YOU WILL UPLIFT HER **FAMILY**. UPLIFT THE FAMILY AND YOU WILL UPLIFT AN ENTIRE COMMUNITY
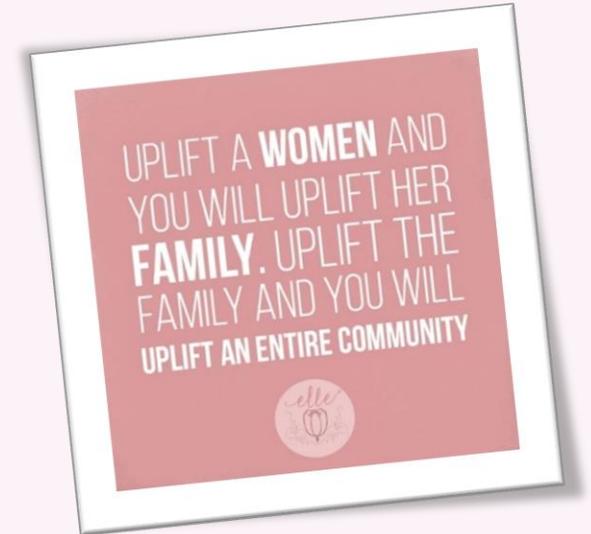
EDUCATION PROGRAMMES

Our programmes are centred on several population groups:

- Girls and Women in Schools

- Women in the Workplace

- Underserved Communities

- Healthcare Providers and Educators

- Innovators and Researchers
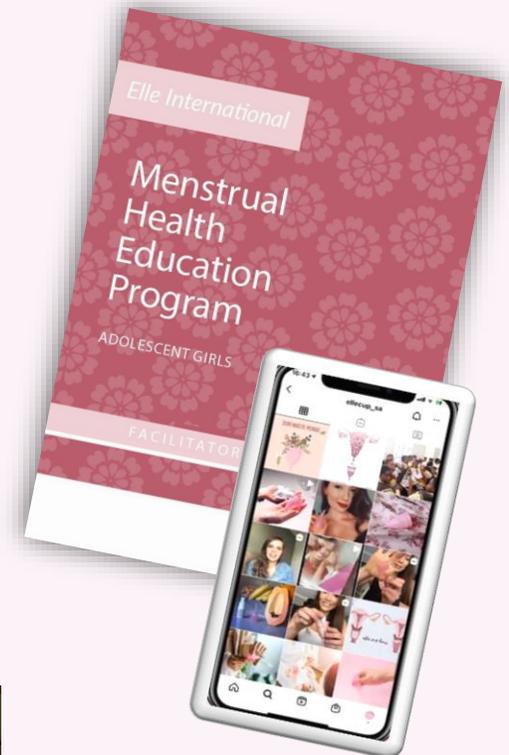
EDUCATION PROGRAMMES

Establish a Health Ambassador at each school:

Immediate stage:

- Champion for women's health.
    - Delivers education and training on menstrual and reproductive health.
- Oversees management of Moxie and provided with usage data.

Later stage:

On-boards students onto the Elle ecosystem.

- Womany
- ElleStudies
- ElleHealth
- Point of contact for researchers and healthcare professionals at the school.
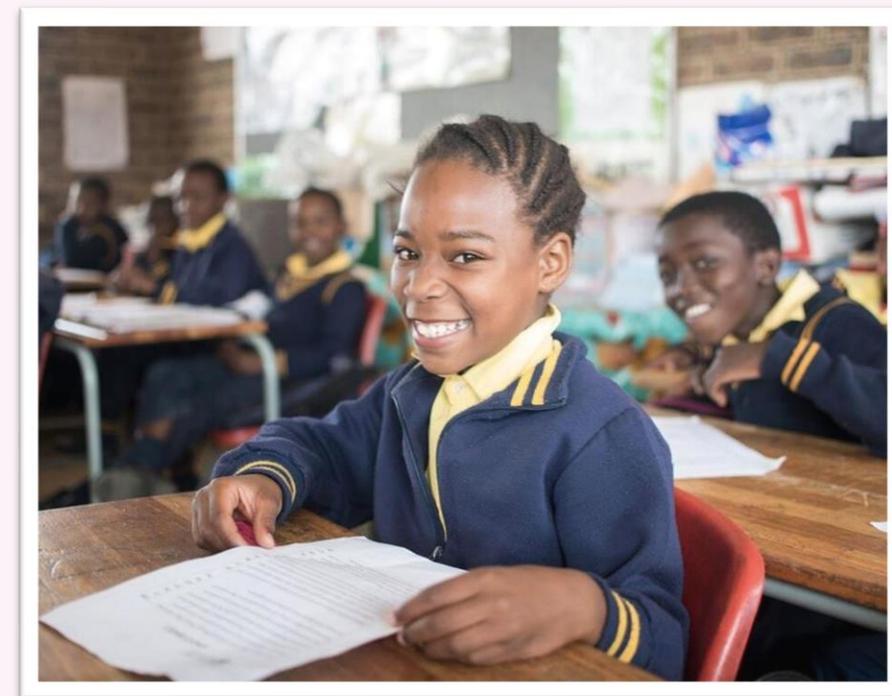
PERIOD CARE TO COMMUNITIES

Assisted

> 60 000

women and girls with menstrual cups and period underwear since inception. Assisting an average of

> 10 000

annually.

Period care interventions across

8

African countries.

Qualitative project focus areas

- Improve access.

- Reduce environmental impact.

- Improve school attendance.

- Reduce stigma around menstruation and safe period care.

- Project concept expansion.

Outcomes:

- 50% increase in attendance during menstruation.

- Nearly 60% increase in girls staying the full school day.

- 84% of girls reported being more confident in dealing with their menstruation.

- 89% of girls reported feeling less ashamed speaking about and seeking assistance concerning their menstrual and reproductive health.

Evidence for assured impact

Elle's integrates evidence into all stages of work, providing assurance for all initiatives. This includes evidence based on individual programme and project monitoring and evaluation to improve impact and drive accountability to programme and project participants.

- **Advocacy:** By demonstrating real-world impact of key issues for women and girls. Elle can provide decision-makers with the information they need to make informed decisions that can lead to effective and impactful policy actions.

- **Continuous Improvement:** With evidenced incorporated into the operational fabric of Elle, it encourages a culture of continuous improvement, allowing for the evolution of strategy based on successes and challenges.

- **Accountability**: The assurance driven approach fosters accountability to the communities Elle engages with, ensuring their needs and aspirations are at the forefront of Elle's work.

- **Programme Design:** Evidence enables the refinement of programme design, to tailor intervention for more effective and relevant initiatives.

- **Improved Decision-making:** Evidence-based decision-making ensures more efficient and effective deployment of resources in all of Elle's initiatives.

Our context

Girls and Women in Schools – Students in schools across Africa face barriers to education due to inadequate menstrual products and health education. Elle is empowering them by providing easy access to essential and sustainable menstrual products through Moxie and by imparting comprehensive education. This support reduces absenteeism, boosts confidence, and improves academic performance.

Women in the Workplace – Women in workplaces often encounter difficulties managing menstruation due to a lack of resources and facilities. By installing Moxie dispensers and fostering a culture of openness and support, Elle is enhancing workplace inclusivity, comfort, and productivity for female employees.

Underserved Communities – Communities in rural and impoverished areas face the greatest challenges in accessing menstrual products and health education. Our efforts using technology reach these marginalised populations, providing them with essential resources and knowledge to manage their health effectively.

Healthcare Providers and Educators – Our comprehensive education component extends to healthcare providers and educators. By equipping them with accurate information and resources, they can better support women and girls in managing their health and addressing broader women's health issues.

Innovators and Researchers – Our holistic women's health solution benefits innovators and researchers invested in solving women's health challenges beyond menstruation. This provides an opportunity to explore, innovate, and contribute to advancements in women's healthcare where solving the challenges in Africa form the basis of a global solution. harmonising fragmented and complex data with AI to empower and support the medical and research communities.

The Elle advantage

Elle's strategy is the result of extensive experience conducting women's health interventions across the African continent. It is an enduring strategy establishing a technology moat around every aspect of the operation. The technology has not existed in a fully integrated holistic solution previously, providing Elle with the motivation for "why now". Strategically Elle's advantage exists in several key areas:

Location economics – Located in a special economic zone combined with fully localised production and a supply chain in a soft currency, confers operational and economic advantages enhancing Elle's competitive position domestically and internationally. The South African Government offers the R&D tax incentive allowing scientific and/or technological R&D in the country to deduct 150% of its R&D spending when determining taxable income.

Supply chain – Located in proximity to the cultivation of numerous organic plant-based fibres ensures a diversity of supply options. Combined with data driven supplier assurance ensures a resilient supply chain.

Moxie – The production line for Moxie has been developed in conjunction with firms responsible for the production lines for the automotive OEM's. As with the product line this ensures the highest quality output at scale, at the lowest production cost. Connectivity within the dispensing unit supports optimisation of inventory levels and product mix, while location services enhance utilisation. The inclusion of integration with Womany incorporates users of the product line into the digital ecosystem, preventing abuse and providing assurance. Moxie itself serves as an effective distribution channel applicable across a diversity of settings, fulfilling a need holistically through the provision of menstrual products, wipes, pain relief, and integration with Womany.

Manufacturing technology – The latest generation manufacturing technology incorporating predictive maintenance and AI driven real-time quality assurance for high efficiency, unrivalled product quality and safety, and the lowest cost of production.

Research – The collection of good quality healthcare data, in a trusted and safe way to revolutionise chronic disease management and tracking, and through which stakeholders can communicate traversing silos to share learning and enhance collaboration across initiatives to improve collective effort.

Womany – The application enables health access and provides multifaceted utility for a diversity of users supporting products, services, and research.

Data management platform – Enables the management of the Moxie network globally, data driven supplier assurance, dataset development and MLOps for AI driven diagnostics, and the next generation of electronic patient health records.

Diagnostics – Accessible, affordable, non-invasive diagnostics for women's health are non-existent in most parts of the emerging world and will be a game changer in alleviating the affliction of millions of women and girls who endure suffering because of a lack of diagnosis. Low-cost testing kits, and no cost AI driven diagnostics through Womany promise widespread adoption and exploit common distribution and engagement channels within the Elle operation, a virtuous cycle that spurs user growth, data growth, and of AI driven services for women's health.

Patient driven data platform – Enables the collection of comprehensive patient data, while preserving privacy, ensuring security, and placing the patient in full control where patients themselves contribute directly to health information.

Treatments – Utilise common engagement and distribution channels, the data and AI capabilities of Womany, and are a natural extension of diagnostics.

Reach – The ability to scale to reach across geographies and beyond menstrual health into maternal health, and women's health more broadly, enabled through resource integration and resource extension from uniting the three sides of women in the marketplace, implementation partners, and academic / research institutions.

Purpose – Elle's greatest asset; people with purpose who have and continue to impact the world around them for good.

The future of Elle

- To position South Africa as the prominent and influential player in the women's health ecosystem globally, **creating opportunities** for the emergence of industries that arise from the convergence of technology, harnessing the transformative potential for economic and societal benefit.

- **Affordability** and **access** are the two major barriers that keep women and girls from getting the products, diagnostics, and treatments they need. Elle's approach will dismantle these barriers and is premised on; **equity enablement**, **climate focus**, **business driven**, and **leading in transformative solutions**.

Product & Services

Six key areas:

| PRODUCT LINE | NONWOVEN NATURAL FIBRES | DISPENSERS | DIGITAL ECOSYSTEM | DIAGNOSTICS | TREATMENTS |

Equity enabled

Innovative approaches to support users in accessing their choice of affordable and safe women's health products diagnostics and treatments.

Climate focused

Solutions that are sustainable with minimal environmental impact (e.g., plastic-free, biodegradable) so they do not become tomorrow's problems.

Business driven

Provide solutions that meet demand long-term, and support R&D for diagnostics and treatments.

Leadership in transformative solutions

To position South Africa as a global leader in women's health for societal and economic benefit.

Elle menstrual product line

- The highest quality and safe.
- Environmentally friendly.
  - Plastic-free and fully biodegradable.
  - No synthetic or semisynthetic fibres.
  - No petroleum based super absorbent polymers.
  - Organic plant-based fibres cultivated in South Africa.
  - No bonding agents.
- Flushable wipes to alleviate burdens on urban and rural sanitation systems
- Fully localised in South Africa to support the South African an international market.
- Utilise the most advanced manufacturing technology.
  - Incorporating AI technology with South African co-development.
  - Ensuring products are accessible and affordable.
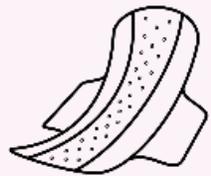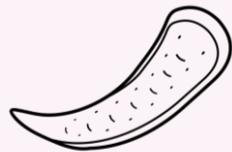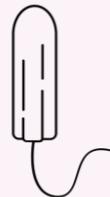
PADS **LINERS** **TAMPONS** **CUPS** **PERIOD UNDERWEAR** **WIPES**

Nonwoven natural fibres

Elle is working with domestic and international partners on the development of the technical natural fibre supply chain in South Africa across the following plant-based fibres:
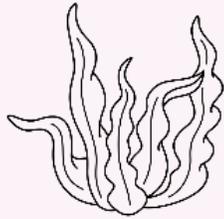
Hemp **Kelp /seaweed** **Bamboo** **Cotton** **Lyocell** **Aloe vera**
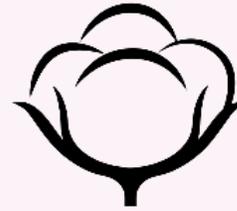
The source of supply includes the following:

- Cotton (Cotton SA)

- Hemp (Eastern Cape)

- Bamboo (Eastern Cape)

- Aloe Vera (Eastern Cape)

- Kelp / seaweed (Eastern Cape)

- Lyocell (Verve Advantage - Sappi Saiccor Mill in KZN)

These plant-based fibres are not only critical to sustainability but provide the necessary antimicrobial properties ensuring the products are of the highest standard and safe for use preserving vaginal flora.

Example sanitary pad

**** Possibility to use: Hemp, Cotton, Bamboo, Lyocell

**** Possibility to use: Cotton

****Topsheet

Embossing*

Engraving channels*

Perfume/lotion*

Backsheet

Extra Thin Core****

Backsheet Release Paper*

Wings*

Wings Release Paper*

Disposable tape*

Pouch*

* = Options
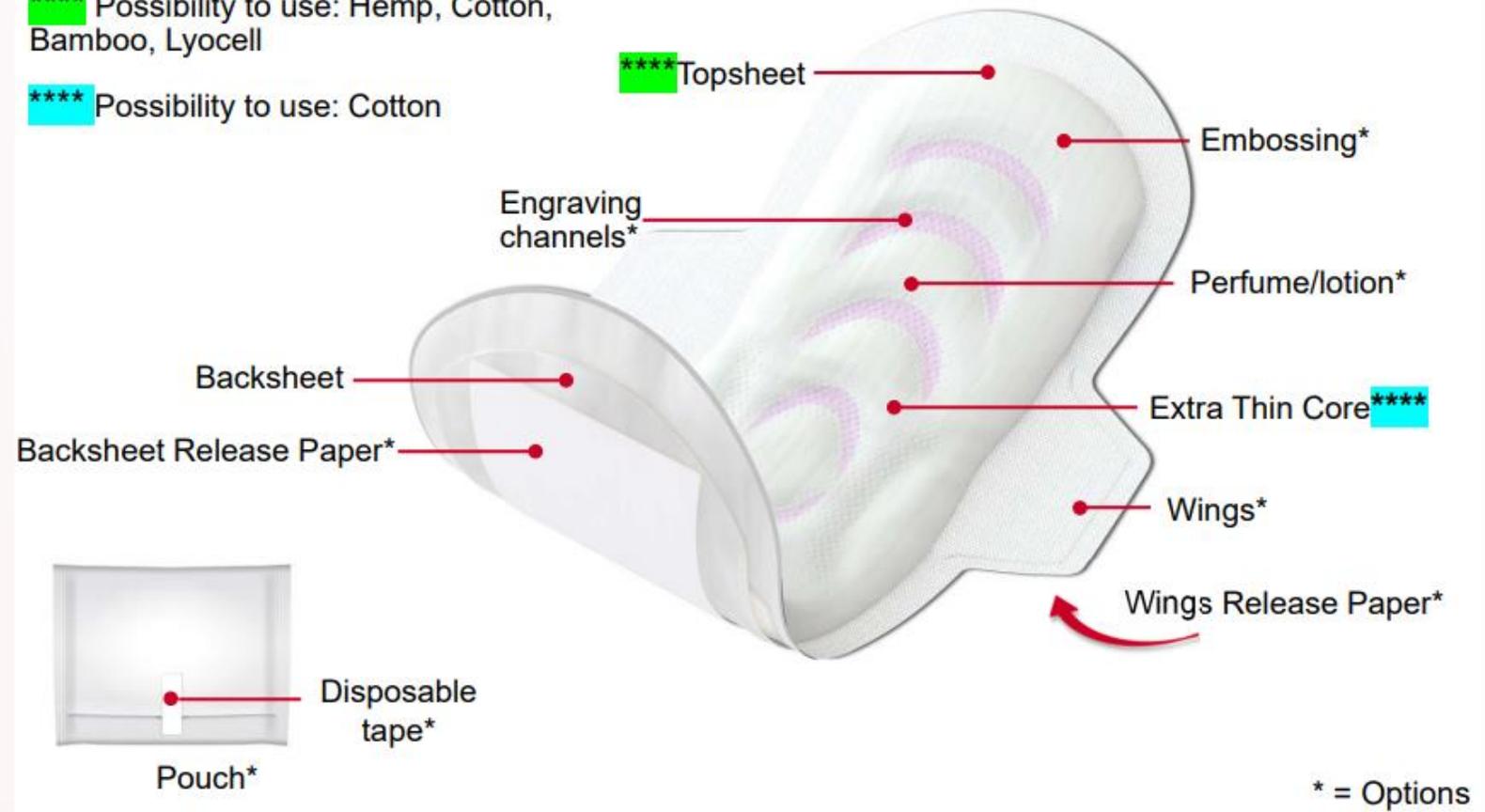
Product line + Measures + Diagnostics

Menstrual blood volume

Through consistent high-quality manufacturing the Elle tampons and sanitary pads can provide women and girls with measures of absorbency. This can assist in diagnosing cases of heavy bleeding and, in turn, undiagnosed cases of adenomyosis, anemia, endometriosis, fibroids, liver and kidney disease, polyps, polycystic ovarian syndrome, pregnancy complications, and even uterine or endometrial cancer.

Topsheet

Soft edge with/without cuff*

Extra Thin Core*

Embossing*

Perfume/lotion*

Wings*

Backsheet

Backsheet release paper*

Wings release paper*
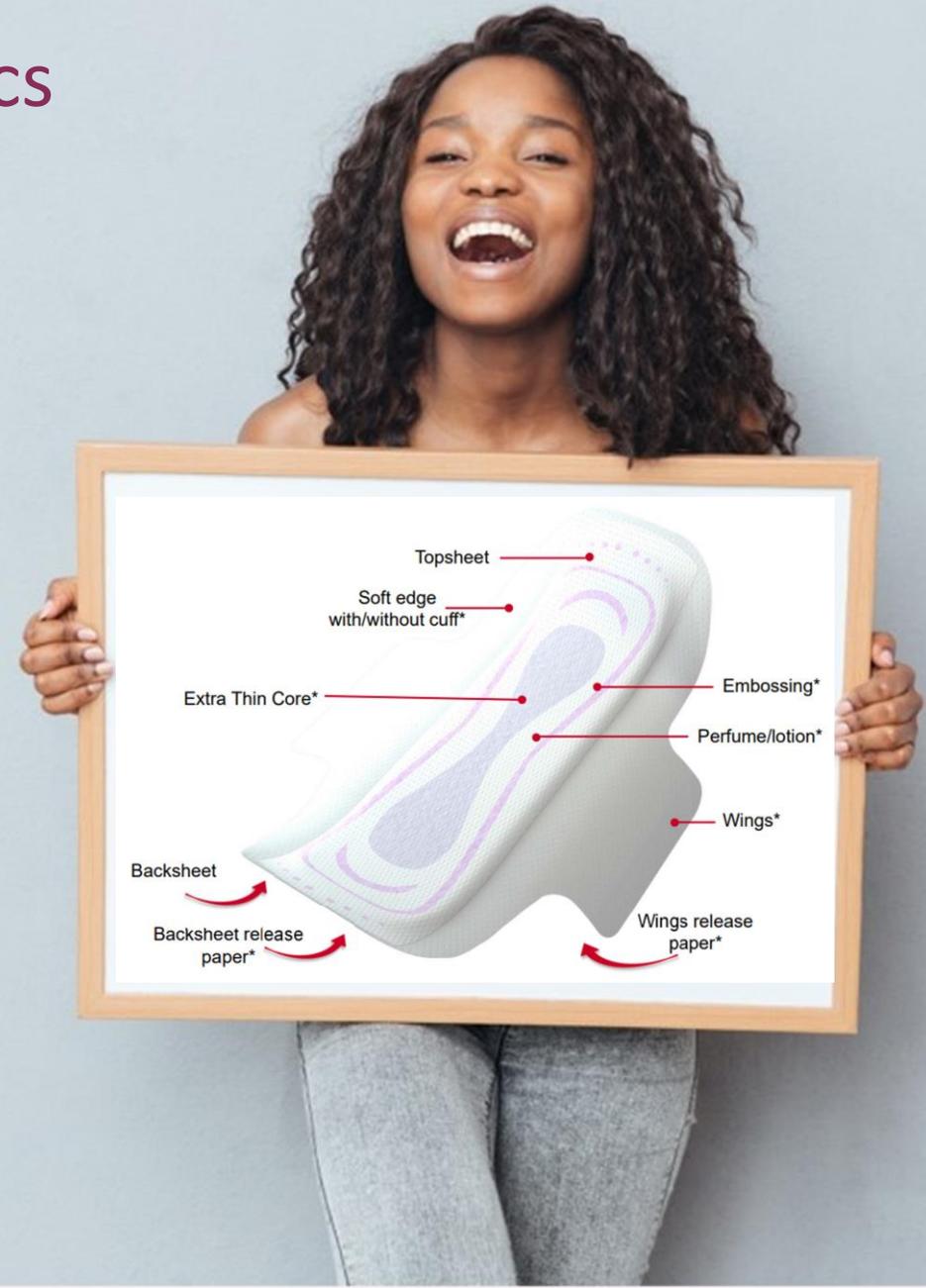
Menstrual blood proteome

Yang H et.al (2012) identified a total of 1061 proteins in menstrual blood, 385 proteins were found unique to menstrual blood.

The detection of a distinct subset of 385 menstrual blood proteins not identified in venous blood or vaginal fluid constitutes an important list of candidate markers.
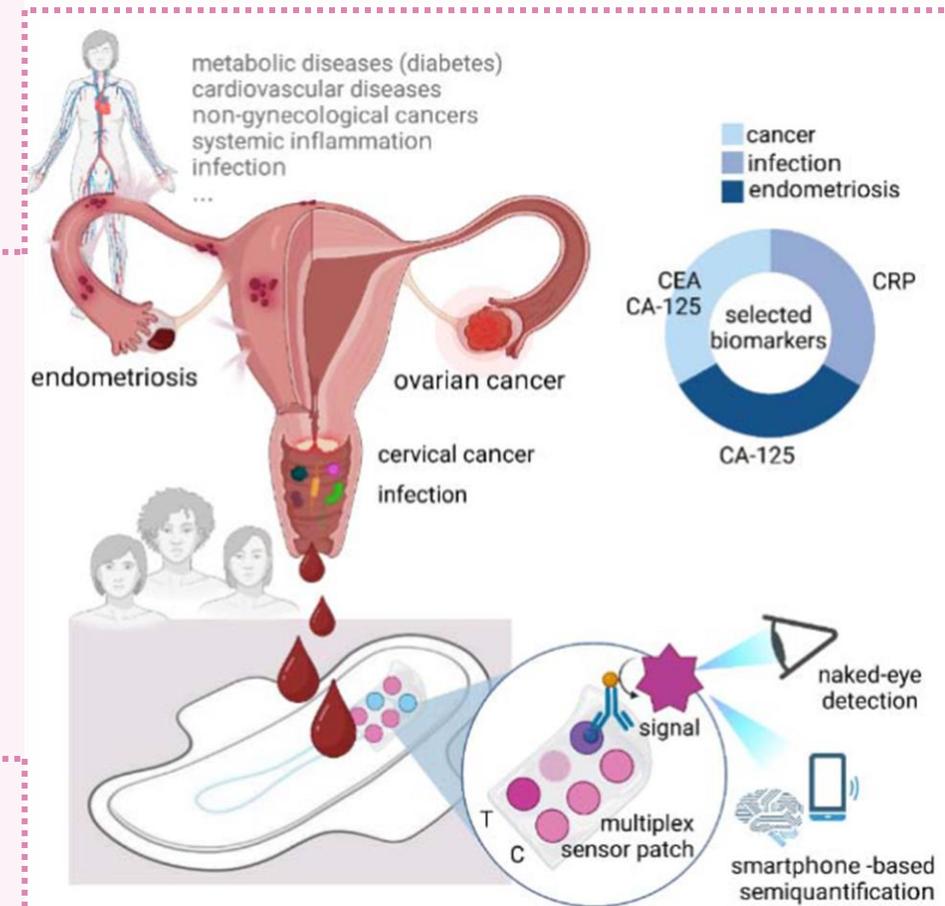
Source: A Wearable In-pad Diagnostic for the Detection of Disease Biomarkers in Menstruation Blood
Dosnon L et.al (2024)

Diagnostics for menstrual effluent

Health domain	Analytes
Anemia	Ferritin
Vitamin D status	Vitamin D
Hormonal health	Thyroid-Stimulating Hormone
Cervical cancer	High Risk Human Papillomavirus
STI	Chlamydia
Reproductive health	Estrogen
Reproductive health	Progesterone
Diabetes	Hemoglobin A1C
Cardiovascular	Low-density lipoprotein
Inflammation	C-Reactive Protein
Fertility and perimenopause	Anti-Mullerian Hormone
Fertility and perimenopause	Follicle-Stimulating Hormone
Fertility and perimenopause	Luteinising Hormone

Together with partners Elle is incorporating diagnostics in the Elle sanitary pads capable of detecting a range of conditions. The in-pad diagnostics integrate with Womany.

Data Driven Supplier Assurance

Sustainability is synonymous with quality and efficiency, permeating the entire operation from providing cultivators of the plant-based fibres with acceptable living conditions, to the appropriation of business proceeds for social impact. To enable digital traceability from farm to the finished products a **data driven supplier assurance** platform based upon an extension of IBM Food Trust will ensure transparent sourcing providing unprecedented transactional data in real time. This, combined with multi-year trade relationships will enable deeper collaboration, enforcing ethical practices in the supply chain, and lay the foundation to address supply chain sustainability issues. The transparent chain of custody will enable consumers to understand the impact of their purchases through Womany.

The AI enabled data driven supplier assurance will improve supply chain resiliency through:

- Improved visibility and proactivity.
- Consolidation and collaboration to optimise fulfilment options.
- Increased traceability through AI assisted establishment and maintenance of records containing Key Data Elements (KDEs) associated with different Critical Tracking Events (CTEs) in the supply chain and supporting GS1 Standards.

Location

The manufacturing facility is under development in South Africa's leading Special Economic Zone – Coega in the Eastern Cape.

Coega SEZ

Go-to-market

Over time the market will extend from menstrual and reproductive health, to maternal health then to women's health in general through both the diagnostics and Womany. Geographical we are working with **multinational partners** to ensure the extension of the Elle product line to international markets, as well as the adoption of Moxie, the diagnostics and Womany. This includes collaborating with firms like Translated to incorporate local languages in the digital ecosystem. Further to this are agreements with academic and research institutions and consortia including the AI Africa Consortium.   We continue to establish **distribution agreements** covering the largest retailers, as well as those in medical and pharmaceutical distribution, and implementation agreements with healthcare non-profit organisations. **Agreements** are under development for both the Elle product line and for retailers' private labels.

If you talk to a man in a language he understands, that goes to his head. If you talk to him in his own language, that goes to his heart.

~ Nelson Mandela

Moxie *the background*

Employees and students endure the repercussions of inadequate women's health support, which not only affects their immediate well-being but also undermines their long-term educational and professional prospects.

In the **employee sphere**, workplace environments often lack adequate facilities and resources for managing menstrual health. Women face obstacles in accessing sanitary products and private spaces, leading to discomfort, anxiety, and compromised productivity.

In the **student sphere**, the burden is equally profound. Many schools in Sub-Saharan Africa struggle to provide adequate menstrual hygiene facilities, resulting in girls missing valuable school days during their periods negatively impacting academic performance and perpetuating educational disparities. Furthermore, societal taboos surrounding menstruation contribute to girls feeling ashamed and isolated, impacting their confidence, mental health, and overall educational experience.

Moxie

- For accessibility of menstrual products in workplaces, schools, public spaces, and communities.

- Networked for efficient stock management.

    - Usage data is used to optimising resource allocation.

- Near Field Communication to control the dispensing of items with Womany.

    - To prevent abuse in environments where the contents are free.

    - Control the dispensing of NSAID's and vaginal rings.

- Supports the redemption of vouchers where contents are subsidised through outside schemes.

- Supports Wi-Fi hotspots in impoverished communities.

- Designed and manufactured in South Africa using the country's automotive supply chain.

    - At least 15 000 units to be manufactured annually for international hygiene and facilities management companies.

Moxie connectivity

Unifies the digital ecosystem of **Womany** with the **Elle product line** and the dispensing through **Moxie**.

Elle is collaborating with leading networking and telecommunications firms on the incorporation of connectivity for the Moxie dispensers. This includes:

Wi-Fi **Mobile** **NFC** **LoRa** **Satellite**

Health system strengthening

Elle's digital platforms form part of commitments to Partner2Connect in provisioning health systems to connect the unconnected to healthcare and improve women's health globally.
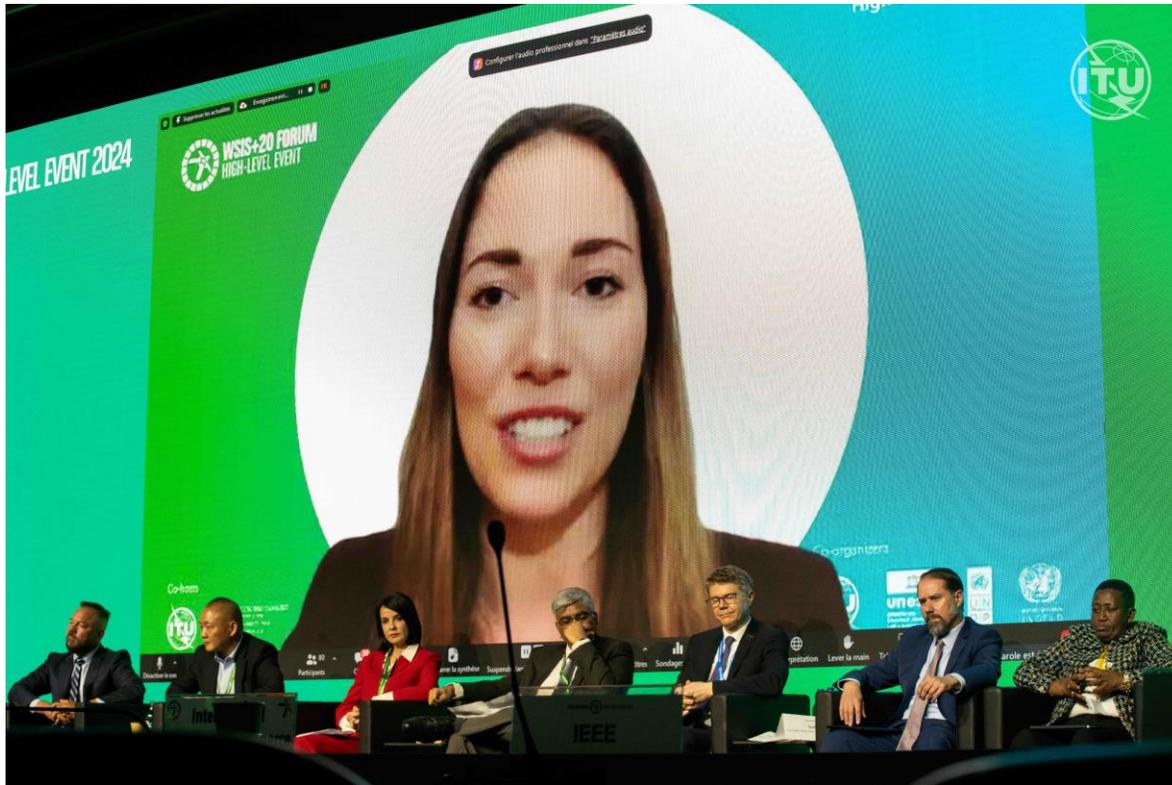
P2C tops USD 50 billion at the WSIS+20 Forum High-Level Event!

At the Partner2Connect High-Level Panel at the WSIS+20 Forum High-Level Event 2024, USD 4.8 billion in investment commitments toward global connectivity were announced, bringing the total pledges aimed at closing the digital divide to USD 50.96 billion, over half the USD 100 billion goal set for 2026.

This milestone is one of the most significant achievements of the Coalition, and we extend our gratitude to everyone who made it possible. The new pledges announced at the WSIS+20 Forum High-Level Event included commitments from: *AT&T, the Government of Canada, Elle International, and Microsoft.*

Find your *Moxie*

Locations services support locating the nearest Moxie dispenser through Womany.

Dispensing

Depending on the model, Moxie supports the provision of:

Sanitary pads

Liners

Tampons

Wipes

NSAIDs: The provision of over-the-counter nonsteroidal anti-inflammatory drugs like Ibuprofen for menstrual related pain.

Vaginal rings: For the effective provision of pain relief and therapeutics to women.
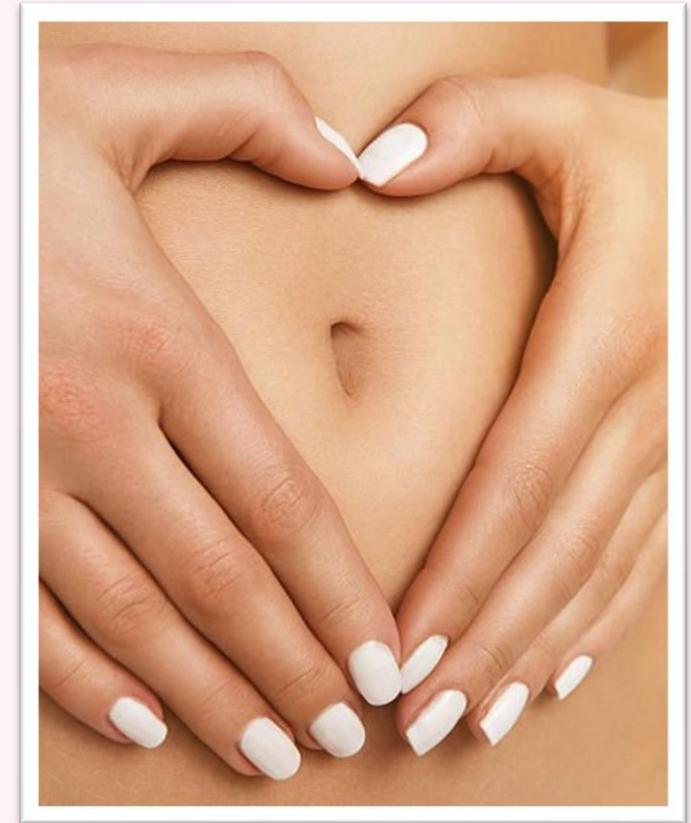
BLOAT B GONE   PCOS B GONE   PMS B GONE

Digital ecosystem

Our approach is not just about providing products or information; it's a holistic, tech-driven ecosystem that transforms how women's health challenges are approached. By blending innovation and technology, we're creating a dynamic and inclusive environment that empowers women and girls with knowledge, resources, and personalised healthcare tools, contributing significantly to health equity and overall women's health in Africa.

Harnessing the power of technology, Moxie is virtually connected to a digital ecosystem including Womany, enabling the unification the three-sided marketplace of **women in emerging markets**, **academic researchers / medical professionals**, and **implementation partners**. By uniting Moxie with Womany, we bridge the divide between the digital world and the world of physical products. Importantly, the digital ecosystem provides the bedrock for the provision of forthcoming AI driven precision diagnostics for related chronic diseases and conditions.

The architecture of Womany, is such that it is based on a data management platform utilised by the world's largest organisations and can be scaled as a platform for next generation electronic patient health records. This provides for the rollout of a unified data platform needed for precision, individual healthcare, and the application of AI services across healthcare broadly. Lastly, Elle is engaged with Africa's leading telecommunications firm for Womany and Moxie deployment in low resource environments.

Womany

Overview:

- Innovative women's health application by Elle International.
- Designed to support women through all stages of life, from menarche to menopause and beyond.

Key Features:

- Personalised Care Plans.
- Cycle Tracking: For example, monitoring menstrual cycles and ovulation.
- Fertility: Predicts ovulation to aid in family planning.
- Educational Content: Best care practices on common health issues like PCOS and endometriosis.
- Disease Detection: Offers tools for early detection and management of gynaecological conditions.

Community Support:

- Provides a supportive community for women to connect and share experiences.
- Offers a platform for women to seek guidance and support from peers and healthcare professionals.

Accessibility:

- Freely accessible to all women, ensuring inclusivity and equity in healthcare.
- Integrated with ElleHealth, ElleStudies, Moxie, and diagnostics for a comprehensive healthcare experience.

Impact:

- Bridge the gap in women's health by providing accurate information and support.
- Empowers women to take control of their health and well-being.
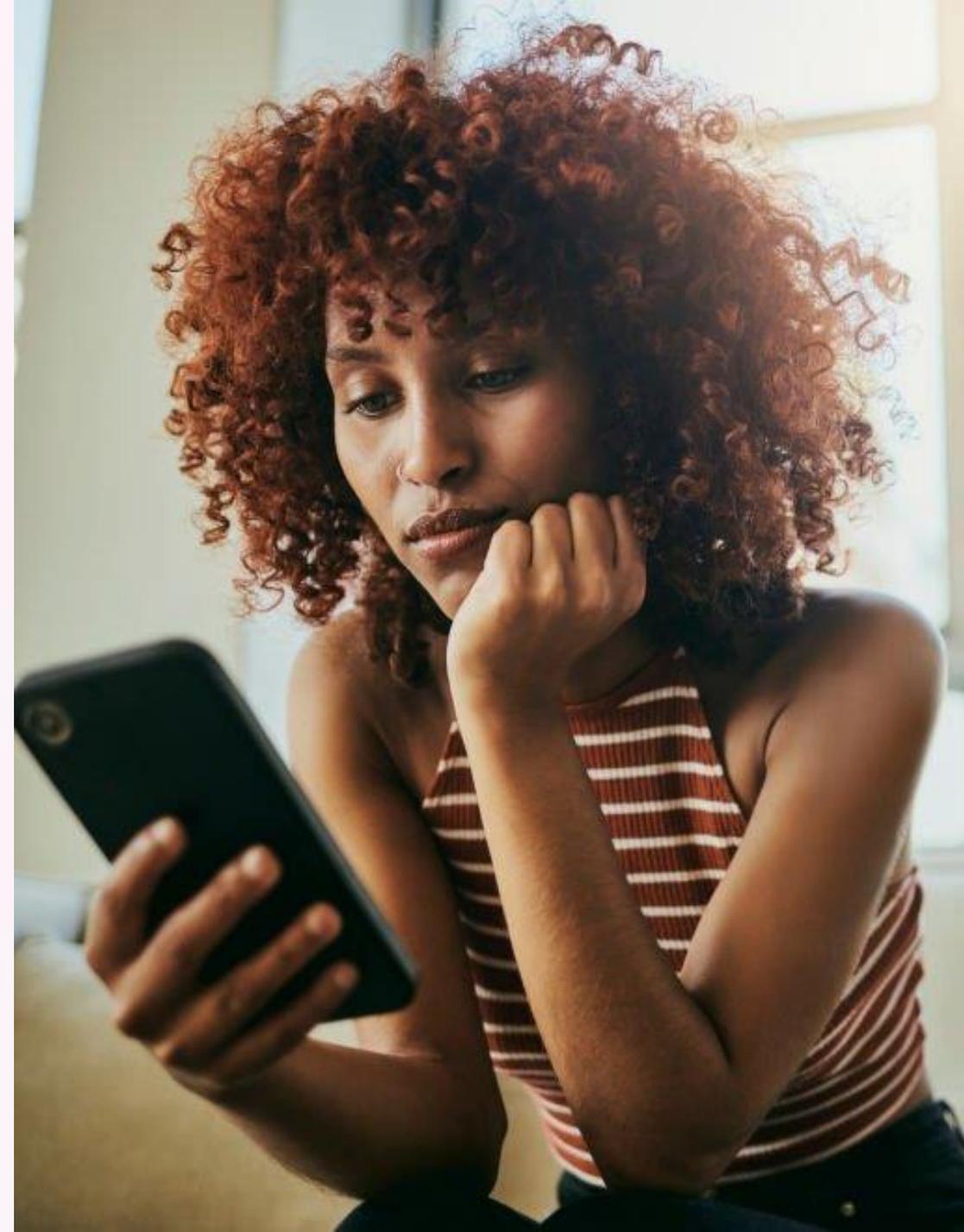
Womany

The Elle mobile application provides a menstrual and fertility calendar that helps to track period and health status, while providing a safety net by analysing inputs and notifying in case of increased chance of a serious gynaecological disease. In such cases Womany connects women and girls to verified information on **best care practices** and medical professionals to guide them on their health journey.

Womany provides medical support by gathering the most important information from a user's posts and makes a **summary** that, if the user provides it to a medical professional, can provide a more accurate picture of the medical condition and better treatment if needed. In time Womany will support AI driven **diagnostic medical reasoning and conversation**, which will be extended to a range of women's health conditions.

As part of the development process, Elle has identified five serious gynaecological diseases to focus on: endometriosis, PCOS, fibroids, ovarian cyst, and pelvic inflammation. To support the detection of these conditions Womany utilises **a symptom-disease classifier**. Womany then monitors whether a gynaecologist is warranted based on the observed symptoms. Womany also pays attention to which diseases it is worth paying special attention to in case of a problem.

Womany supports the monitoring of self-reported mental health (e.g., stress, anxiety, and depression), physical activity, and environmental factors to classify any **behavioural patterns** underlying clinical manifestations of menstrual diseases and disorders related to fertility issues, stress, nutritional and other lifestyle factors.

Womany assists users in how to manage and reduce the negative physical, psychological, and social symptoms of various menstrual diseases and disorders by encouraging new skills acquisition and adaptive behaviour changes to **improve quality of life**.
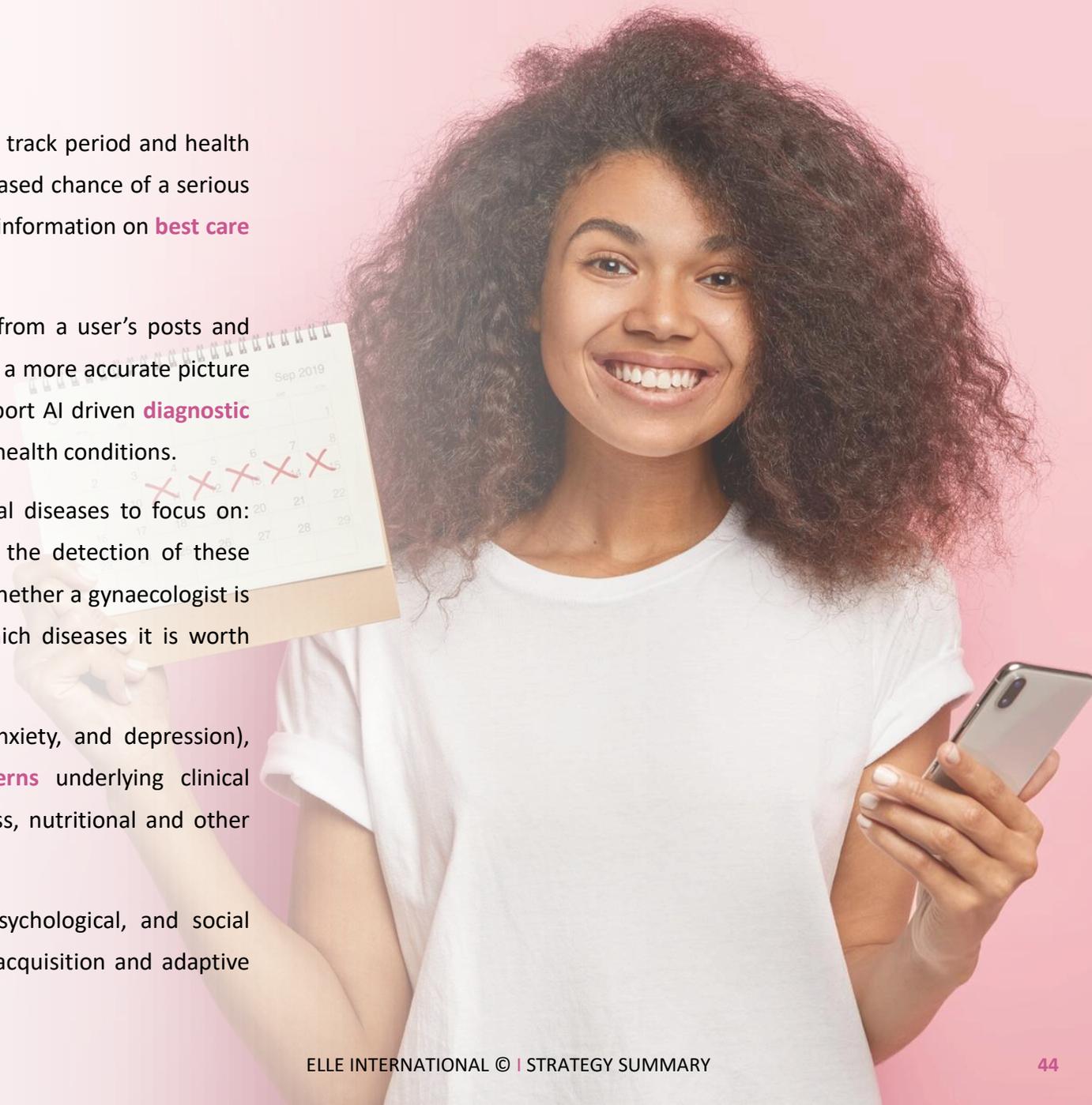
# Diagnostic medical reasoning and conversation
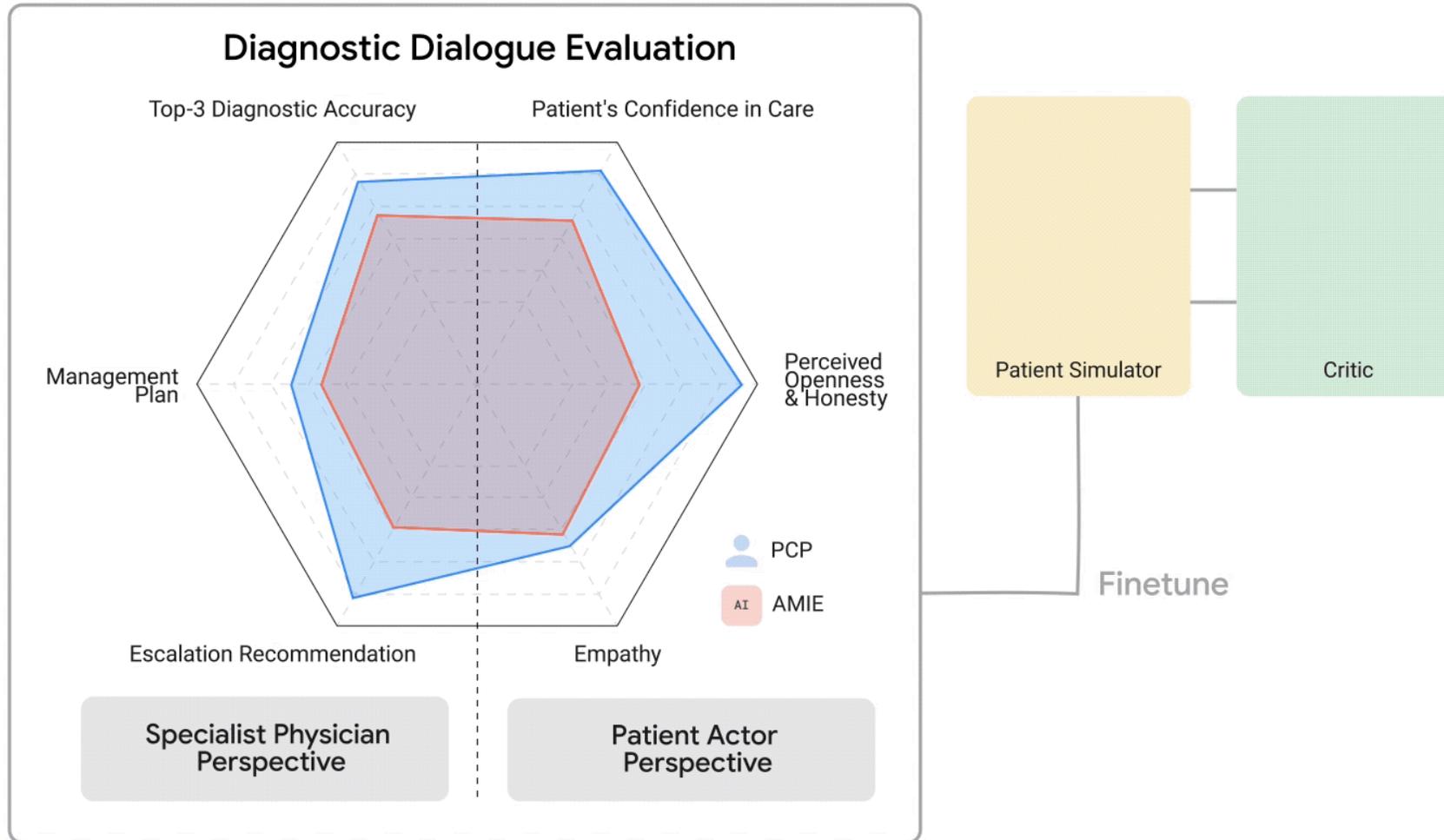
Scaling

Womany and the AI driven diagnostic services provided through it are free. Revenue from the Elle product line will support the development and maintenance of Womany. Where product line costs scale near linearly with each additional unit, the costs for Womany and AI driven services do not, enabling rapid deployment at scale without the associated increase in costs. Every 18 months, Elle will produce over **1 billion** individual items across the product line. This output in conjunction with Moxie, and the provision of diagnostic services at no charge, will drive significant adoption of Womany. The target lower bound of active monthly users on Womany within 4 years is **30 million**.

The architecture of Womany is based on an enterprise scale **data management** platform. **Differential privacy** and **federated learning** enables the data to be utilised for research, and the provision of AI services in a **privacy preserving** manner.

ElleHealth *the background*

▪ Low- and middle-income countries (LMICs) are plagued by weak primary healthcare systems and poor digital infrastructure. No digital health records exist for individuals in Sub-Saharan Africa. The result is **centralised datasets** and **trusted resources** for patients and investigators are sparse, fragmented, and not shared among the communities they are meant to serve. Data management platforms to create a **unified health record** through data ingestion and to provide data governance to store, manage, share, find and use data critical for the implementation of AI in healthcare are beyond reach for LMICs. This ultimately costs lives and precludes LMICs from participating in innovative R&D and realising benefits in the full potential of technological advances in healthcare.

▪ The impact of digital technologies on the lives of women and girls, particularly in relation to sexual and reproductive health and rights (SRHR), must be placed at the start of the effort to avoid the structurally flawed approach that over time leads to a proliferation of data silos. Under such conditions the collection, storage, and use of personal health data may happen without **adequate consent** or even awareness. **Unauthorised access** and use may have harmful consequences for individuals, particularly for women and girls. Further, the deployment of algorithms without **transparency** and **accountability** can perpetuate bias and discrimination, amplifying existing health disparities. Lastly, implementation must support related products and services for the assured provision of such products and services.
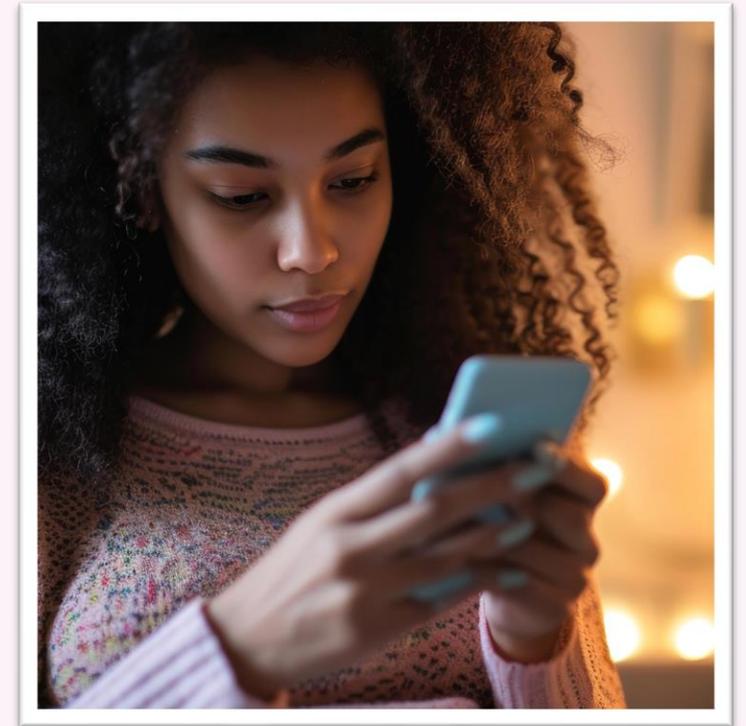
ElleHealth

Summary attributes:

- Enables the collection of comprehensive patient data.

- Privacy preserving, ensuring security, and placing the patient in full control.

- Patients themselves contribute directly to health information.

- Next generation electronic patient health record for the provision of precision, individual, AI based healthcare services.

- Supports data ingestion to create a unified health record and data governance to store, manage, share, find and use data critical for the implementation of AI in healthcare.
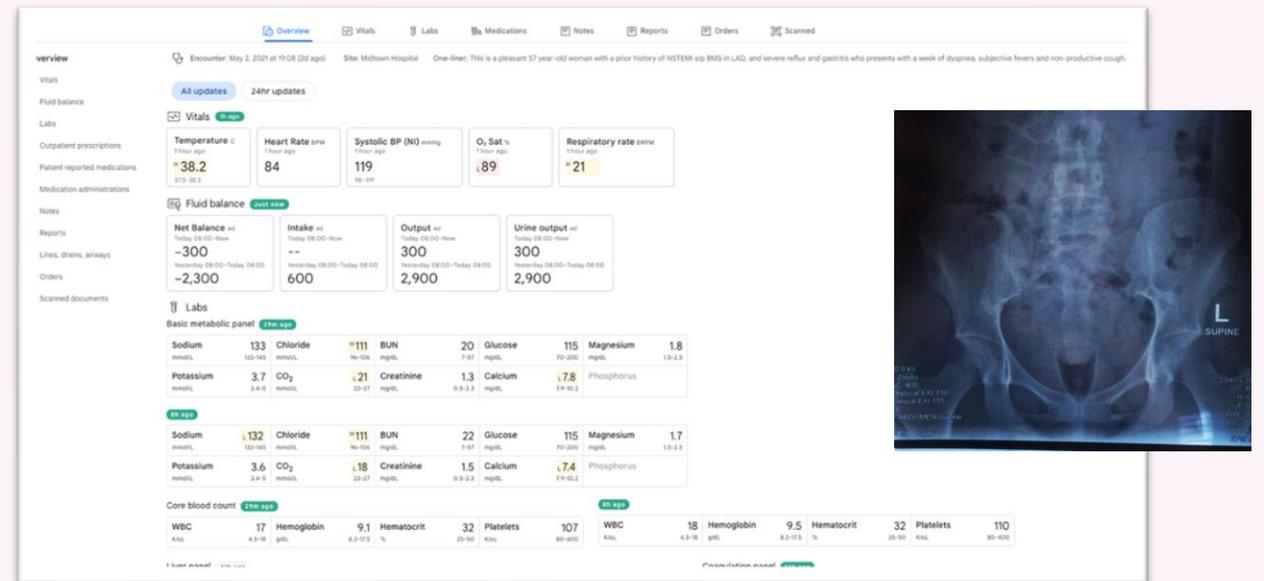
Healthcare Natural Language

Elle's digital platforms deploy **Healthcare Natural Language** which utilises natural language models to extract healthcare information from medical text, including:

- Medical concepts, such as medications, procedures, and medical conditions.

- Functional features, such as temporal relationships, subjects, and certainty assessments.

- Relations, such as side effects and medication dosage.

The platforms are secure and compliant, utilising industry-standard protocols and formats for ingesting, transforming, storing, analysing, and integrating healthcare data, supporting:

- Machine learning.

- Data-level integration of healthcare systems.

- Secure storage and retrieval of healthcare and life science data, including electronic protected health information (ePHI) and other forms of Personal Identifiable Information (PII).

- Digital Imaging and Communications in Medicine (DICOM).

- Fast Healthcare Interoperability Resources (FHIR) DSTU2, STU3, and R4 standards.

- Health Level Seven Version 2.x (HL7v2).

- Unstructured text.
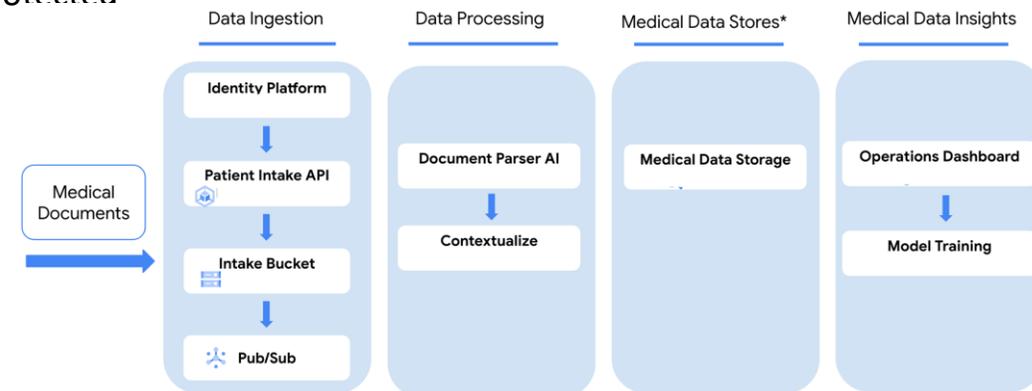
Elle Diagnostics

Increasing pressures on healthcare systems and a need for **accessible**, **non-invasive**, and **affordable** diagnostics; it is crucial that South Africa plays a role in developing and deploying solutions. Where the solutions developed have global relevance and accrue returns to the country. Revenue from the Elle product line will be used to support the development, manufacture, and distribution of AI driven precision diagnostics for related chronic diseases and conditions. While the AI driven diagnostics provided through Womany will be available at no cost, manufactured diagnostic test kits will accrue revenue.

Supported by the deployment of Womany, ElleStudies and ElleHealth, precision diagnostics will initially focus on **menstrual** and **reproductive health**, followed by **maternal health** and then more broadly on **women's health** and bridge gaps in accessing quality healthcare services. Following diagnostics for endometriosis, diagnostics incorporating AI will follow for:

- Polycystic ovary syndrome (PCOS)

- Myomas

- Ovarian cysts

- Pelvic inflammation

- Diabetes

- Insulin resistance

Commencing with endometriosis the intention is to support:

- The manufacture and distribution of **assays**, combined with an AI diagnostic model.

- **Endometrial biopsies** combined with AI based imaging of the histology and an AI diagnostic model.

- **Ultrasound** combined with AI image processing and an AI diagnostic model.

- **MRI** combined with AI image processing and an AI diagnostic model.

The AI models and related artifacts will be open sourced and accessible through an AI medical library. Elle is collaborating with MLCommons on the library.

ML benchmarks

Our approach is founded on generating equitable outcomes. The open-source and open-science approach is critical to improve outcomes for advancing diagnostics, treatments, and pathways to cures.

Benchmarking enables:

- Metrics to support scientific discovery.

- Exemplars across a range of conditions.

- Encourage use of <u>FAIR metadata</u> and reproducible results.

- Enable educational use of resources by researchers with rich documentation and experience records.
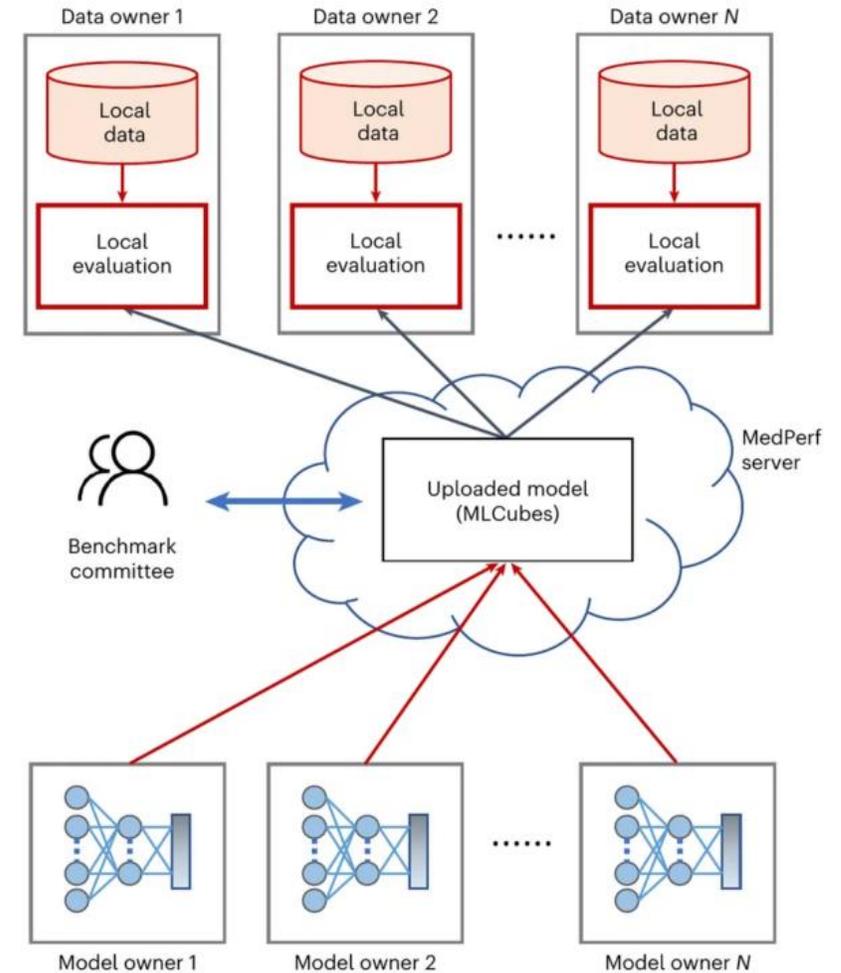
ML benchmarks

The benefits of benchmarking include:

- Baseline performance on a given problem sets a target.

- Encourages the community to "develop" better methods.

- Availability of curated datasets increases openness.

- Fosters more efficient data-intensive scientific discovery.
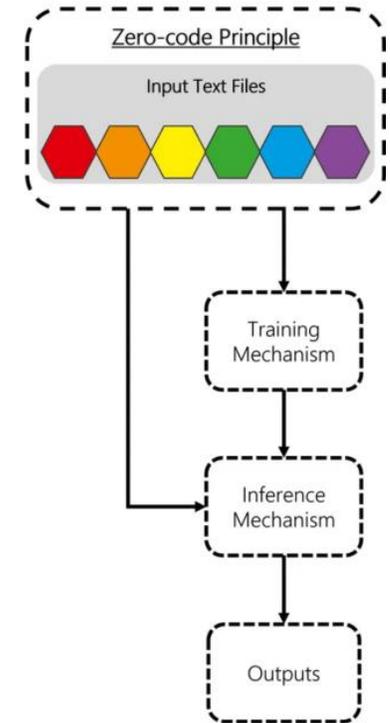
Data governance

Elle employs ethical and responsible data practices in the deployment of digital platforms with the implementation of The Fair Information Practice Principles (FIPPs).
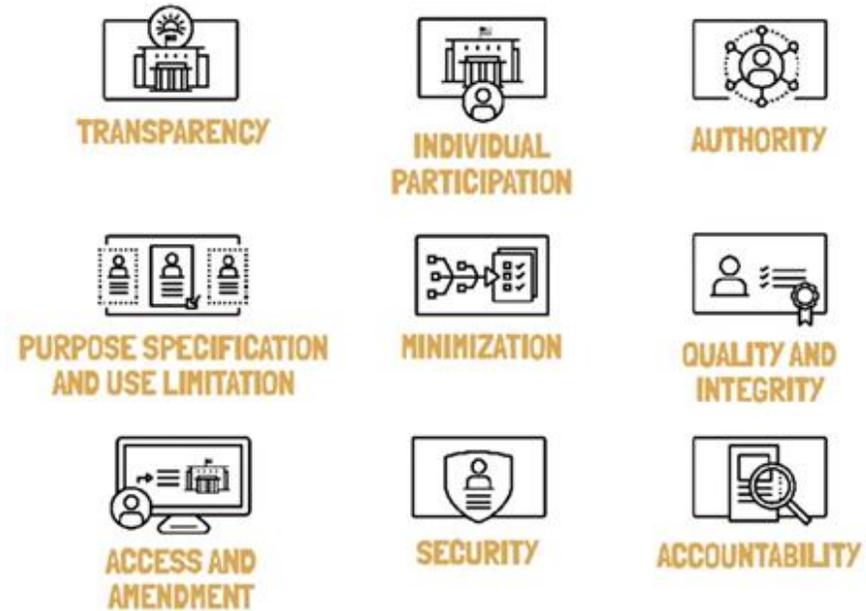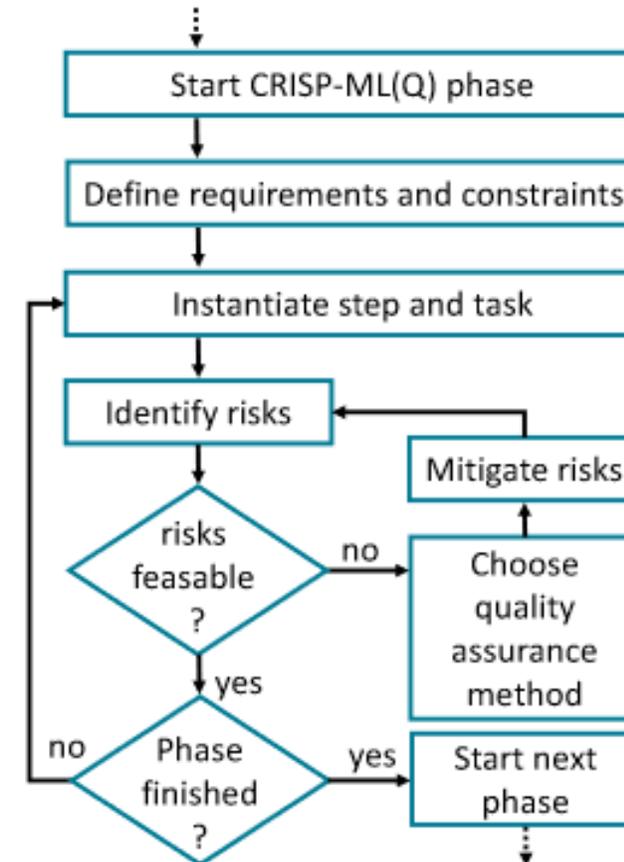
ML quality assurance

Elle utilises a CRISP-ML(Q) methodology for quality assurance in machine learning deployments. The process model describes six phases:

- Data Understanding.

- Data Engineering (Data Preparation).

- Machine Learning Model Engineering.

- Quality Assurance for Machine Learning Applications.

- Deployment.

- Monitoring and Maintenance.

Why Endometriosis?

Endometriosis is a significantly overlooked disease that affects **at least 10%** of women globally, impacting both their physical and mental health, with around **86.5%** of patients experiencing depressive symptoms. The condition's profound effects are exacerbated by an average diagnostic delay of **11 years**, severely disrupting patients' daily lives, including work, school, and personal relationships. This prolonged delay often stems from a lack of training among primary care providers in recognising the early signs of endometriosis.

To address the gap early detection and intervention, Elle is extending diagnostic tools through its digital platforms to patients and care providers with essential information to identify early symptoms of endometriosis. This extends to pre-teens and teenagers to help them distinguish between normative versus atypical period symptoms.

Many women experience challenges in clinical settings as women's pain is minimised and considered over-reactions. These experiences strain the patient-provider relationship as physicians view women as incapable of giving knowledge about their bodies and women, in turn, feel misunderstood and unheard. In addition, in low-and-middle-income countries many women and girls lack affordability and access to primary care providers. To combat these challenges, Elle's diagnostic tools enable at-home diagnosis, reducing dependence on primary care providers, promoting confidence, self-advocacy and providing women with agency over their health.
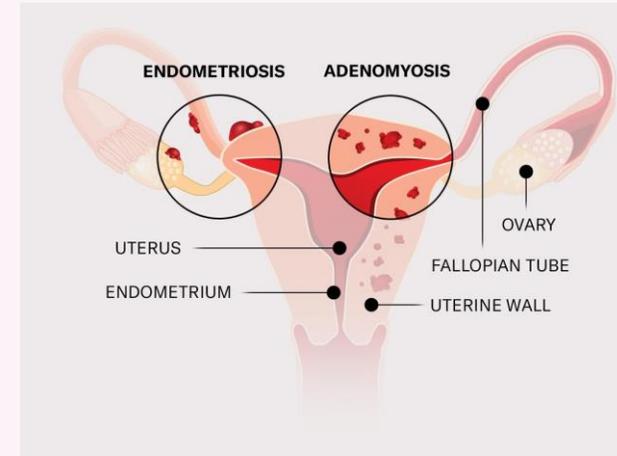
*Credit: New York-Presbyterian's Health Matters*

At-home

Elle is working with partners on bringing to market two non-invasive at-home diagnostics for endometriosis.

At-home assay

- To measure the presence of biomarkers in menstrual effluent.

- The assay results are combined with an AI model that analyses clinical symptoms.

- Synthetic biology is used to produce full length antibodies in a specific strain to reduce the cost and improve accessibility of the assay design.

- The assay utilises gold nanoparticles for detection.

Biosensor

- Utilises nanotechnologies to create a biosensor for biomarker detection.

- The biosensor utilises gold nanoparticles due to their speed of synthesis, high conductivity, and ease of antibody labelling for biomolecule detection.
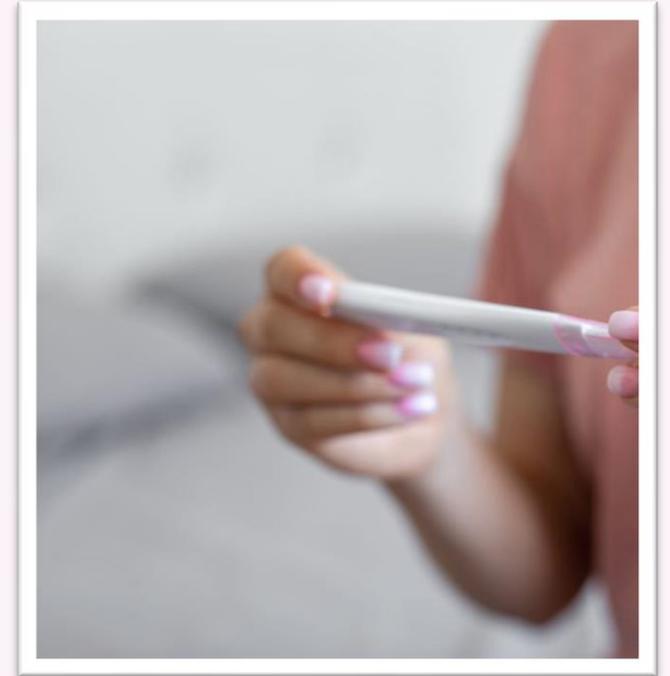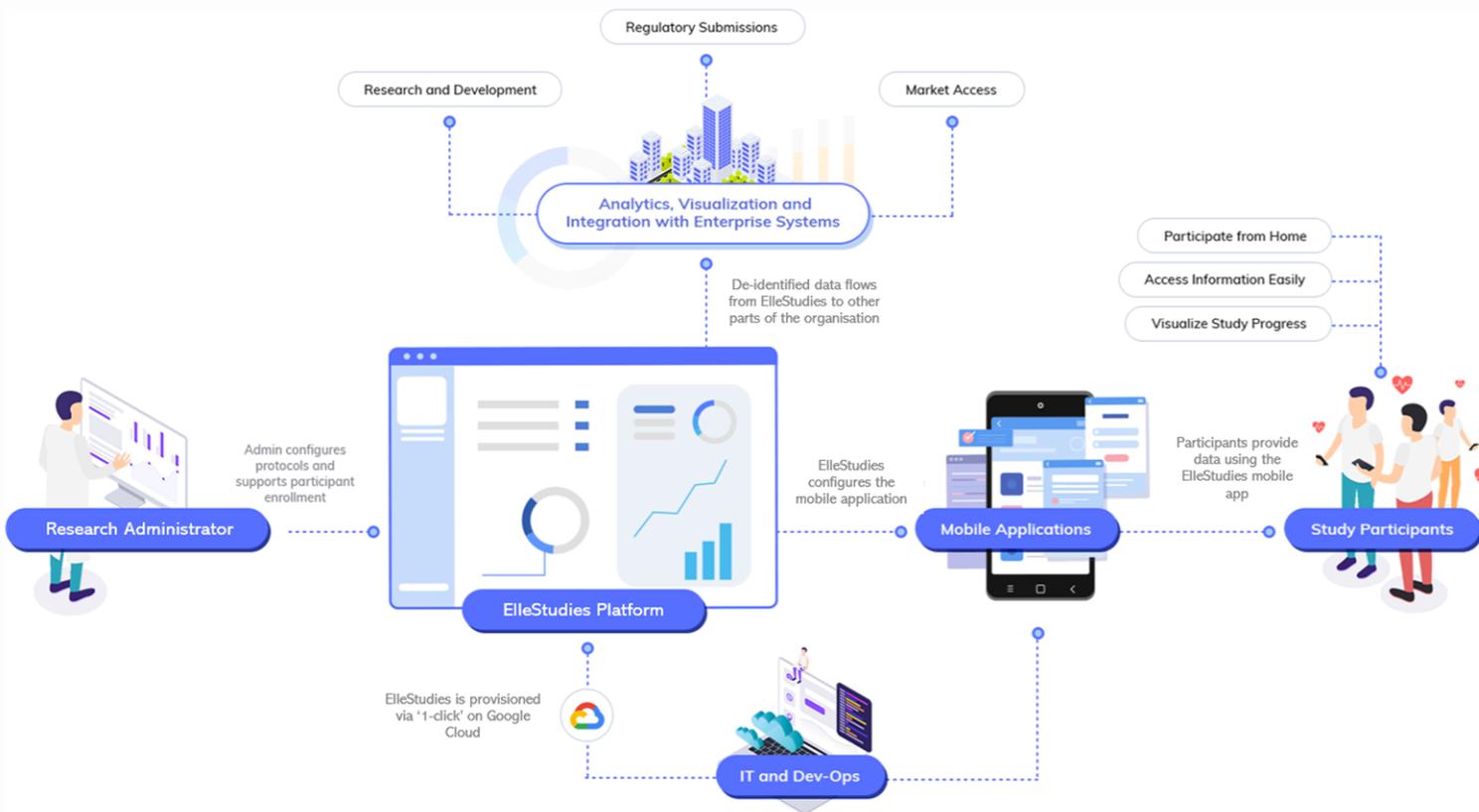
ElleStudies

The ElleStudies platform enables the collection of good quality **healthcare data**, in a trusted and safe way to revolutionise the management and tracking of **menstrual health disorders**, and other chronic diseases. ElleStudies provides the platform through which stakeholders can communicate traversing silos to share learning and enhance **collaboration** across initiatives to improve collective effort.

ElleStudies connects patients to verified information on best care practices, medical professionals, clinical trials, and similar patients near them to **create community**.

ElleStudies places patients in the driver's seat, able to dictate if they want to share their data, raise their hand to be contacted by clinical trial coordinators, and contact specialists or patients like them for care advice.

ElleStudies aims to **democratise** exceptional **care** and the **research** process to accelerate effective diagnostics, treatments, and cures for women's health disorders.

The platform has been designed to support auditing requirements for compliance with the United States Code of Federal Regulations Title 21 Part 11, allowing the platform to be used for trials under Investigational New Drug (IND) oversight.

ElleStudies

Often research and clinical trials are not representative of the **diversity** of the **disease**. Elle believes that universal participation in data collection from all demographic groups is essential to **embed equity** into this next chapter of healthcare. ElleStudies addresses representation and equity for **research recruitment** that more accurately represent the diversity of disease. With ElleStudies we reach communities and focus on the **inclusion** of demographic groups who typically do not participate in research because of barriers created by lack of access to researchers and clinicians, cultural considerations, or low levels of medical literacy.
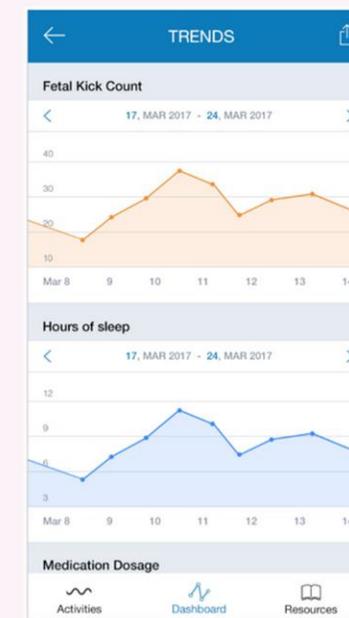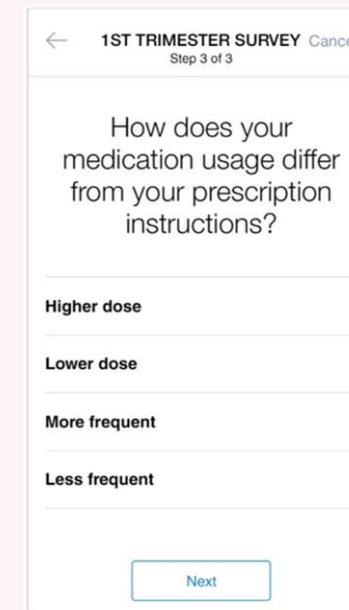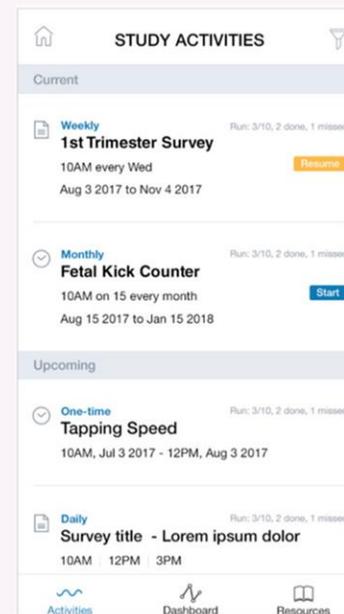
Digital platforms: Future directions

- Support a women's health **medical reporting platform** for healthcare professionals to know about the newest best practices, symptoms, or side effects they notice in women populations.

- Research nuances in women receiving **psychotropic therapies**, specifically measuring **hormonal levels across the menstrual cycle** (e.g., estrogen, progesterone) and life course to determine the potential impact on pharmacodynamics and medication efficacy.

- Diagnostic and monitoring tools for **PTSD**, **PMDD**, **depression**, and **anxiety** for use in low-resource settings by medical professionals and individuals.

Treatments

As part of newly established efforts to manufacture and distribute the most important drugs for Africa in Africa, Elle is working to identify the foremost candidate drugs for manufacture (with partners in South Africa) for women's health conditions. The distribution network for this non-profit Africa pharmacy is well established and has been utilised extensively for HIV and COVID programmes amongst others. In addition to drug treatment, Elle will be providing the menstrual health products, Moxie, diagnostics, Womany, ElleHealth in support of this and other like operations.

Elle treatments

Condition	Form
Atrophic Vaginitis	Gel
Bacterial Vaginosis	Tablet for vaginal insertion
Vulvovaginal Candidiasis	Capsule for vaginal insertion
Polycystic Ovary Syndrome	Tablet taken orally
Premenstrual Syndrome	Capsule taken orally
Premenstrual Dysphoric Disorder	Capsule taken orally
Perimenopause	Capsule taken orally

Treatments for additional conditions in women's health are under development driven by a focus on safety, efficacy, affordability, and access.

Treatments: Future directions

GLP-1 agonists

- Glucagon-Like Peptide-1 agonists work by activating the GLP-1 receptor.

- We are pursuing approaches that have modulatory effects on GLP-1 expression and secretion.

Elle Sub-Saharan Africa Consortium

Elle International is the public benefit organisation leading the Elle Sub-Saharan Africa (Elle SSA) consortium. Elle SSA has initiated collaboration linking institutions in low- and middle-income countries across **academia**, **government**, and **industry** to create a powerful nexus to **democratise data**, **AI technologies**, and the implementation of solutions to support accessibility of essential services to vulnerable communities, especially women.

Scaling involves growing strategic partnerships, extending community engagement, and rigorous monitoring to ensure maximum impact. Next steps are a phased rollout of pilots, robust user education, and continuous improvement based on user feedback and impact evaluation.

Elle International will serve as the **custodian** assuring the development and management of **healthcare data at scale**, while preserving **privacy**, ensuring security, and placing the **individual in full control**. As part of this Elle SSA intends to undertake collaborations with SSA based collaborators for the open sourcing of AI models and related artifacts trained on the data utilising differential privacy and federated learning. The AI models are intended as benchmarks to advance **diagnostics**, **treatments**, and **cures**, commencing in **women's health**.

To build a bridge between individuals, research and industry, strong continuing support is needed and to this end Elle SSA is exploring a venture business model that incorporates:

- Sharing in the intellectual property of research commercialised from the data.

- Charging industry partners a fee to access and analyse the data when bringing new therapies to market.

- Licensing the platform to other non-profit medical research foundations.

Key targets

> 1 billion individual menstrual health items manufactured every 18 months.

> 15 000 Moxie dispensers manufactured annually.

> 30 million monthly active users across the Elle digital ecosystem within 4 years.

Deployment of diagnostics **for at least 15** parameters of women's health within 5 years.

> 300 new jobs created in South Africa.

Beyond 5 years

Beyond five years the strategy is to accelerate the advancement of the Elle digital ecosystem, specifically the diagnostics and AI services. This will entail scaling the deployment scope of Womany, ElleHealth, and ElleStudies to provide the datasets for training and inference for the implementation of AI services in support of a healthcare model providing predictive, preventative, and personalised care. Two key attributes of the Elle ecosystem are fundamental to achieving this, namely the **data management architecture**, and the vast **deployed user base** across the Elle digital ecosystem. Through harmonising fragmented and complex data with AI, and responsibly monetising returns from empowering and supporting the medical and research communities, Elle will be well positioned to revolutionise healthcare where providing solutions for resource constrained rural and impoverished communities serves as a model for the rest of the world. While it is easy to speak of such things, we have taken concrete steps towards realising these objectives. In addition, several multinationals are partnering with us to bring these objectives to fruition.

Following five years of deployment as a platform for next generation electronic patient health records in Sub-Saharan Africa, the lower bound estimate of the data value is **113 million** USD annually. Based on research work with a Big Four professional services firm, within 10 years of deployment the annual revenue is expected to exceed **1 billion** USD. Crucially, the services through the platform are provided at no charge resulting in significant economic and societal impact for rural and impoverished communities.

Our collaborators
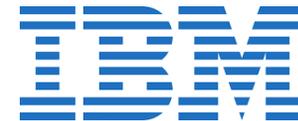
All donations to the Elle International non-profit organisation are tax deductible.

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