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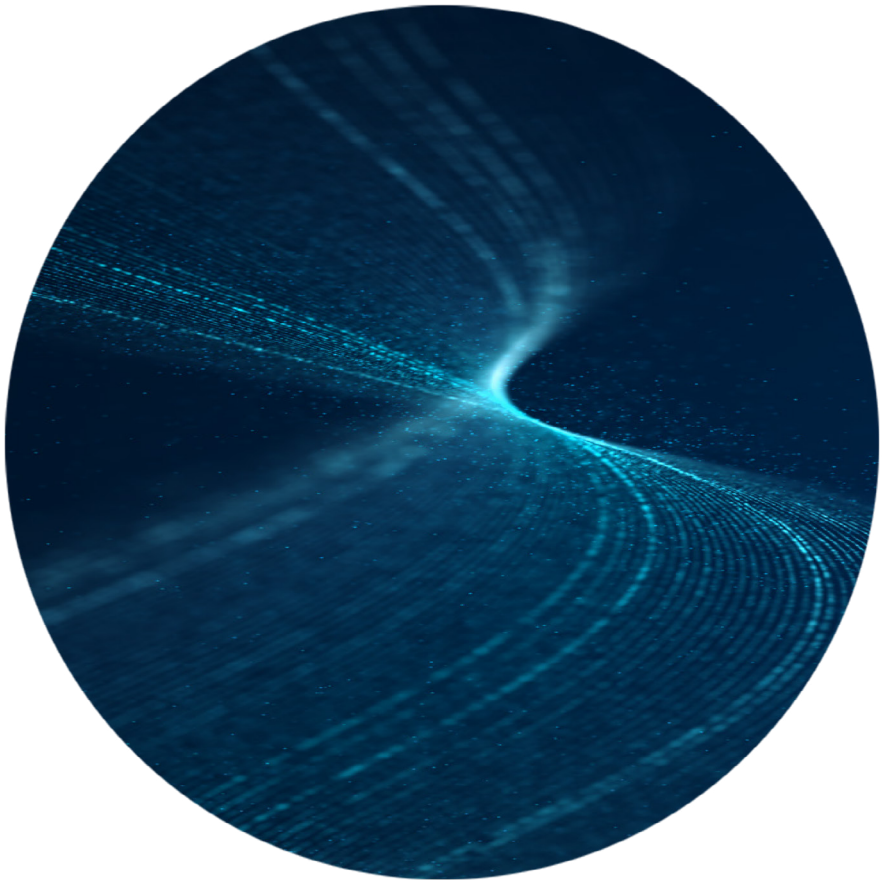

FINANCING INNOVATION IN WOMEN'S HEALTH

A PATH TO ADDRESSING DISPARITIES AND ACCELERATING INNOVATION

NOVEMBER 2023

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This paper explores the challenges and opportunities in financing innovation in Women's Health. Despite significant unmet medical needs in female-associated diseases, funding research and development (R&D) in this area have been historically limited. To foster innovation, this paper proposes a comprehensive approach, including policy making, public investment, and collaborative efforts, inspired by successful models in other fields such as orphan drug development.

Disclaimer: Women's Health is a general term used to describe indications and diseases that affect uniquely, differently or disproportionally people with uteri, who may or may not identify as women.

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1. Context

Women's Health encompasses a broad spectrum of diseases and conditions that may either:

01 be exclusive to females,

02 be more prevalent in females or

03 impact females differently and/or disproportionately;

The exact boundaries of this definition remain somewhat ambiguous, allowing for the inclusion of diverse medical indications and terms. Despite the significant unmet medical needs within this field, Women's Health (defined as above) has not received the attention obviously warranted in terms of research funding, for instance, accounting for only 10.8% of NIH funding[3]. Similarly, the biopharma industry has invested merely 4% of its resources, with the majority being directed towards cancer research[1]. Recognizing these critical shortcomings, and drawing parallels with other therapeutic areas, that produced innovative drugs that addressed significant unmet needs and also achieved commercial success is crucial.

To discuss an actionable roadmap forward, catalyze change and raise awareness for the Women's Health field, stakeholders spanning various sectors of the R&D value chain (including researchers, biotechs, pharmaceutical industry, and investors) convened on June 7, 2023 at the *FemTechnology* Summit in Basel, Switzerland. This paper presents the outcome of those deliberations as well as further discussions with Key Opinion Leaders, and outlines the proposed strategies for advancing research and development in Women's Health.

2. Current status of Funding Innovation in Women's Health

How relevant is the definition of Women's Health to Leverage Biomarkers in Drug Development?

Properly defining Women's Health can be a complex task. While reproductive system-associated diseases have been the obvious indications used to define Women's Health (e.g., female infertility, Endometriosis, Polycystic Ovarian Syndrome) to date, the field now agrees that a true definition of Women's Health should expand to indications more prevalent in females (e.g., Multiple Sclerosis, Alzheimer's disease). Nevertheless, there exists a substantially bigger set of indications that can be categorized under the Women's Health umbrella. In essence, any condition in which women exhibit distinct symptoms and responses could be considered within the realm of Women's Health, including diabetes and cardiovascular diseases, for example, which would in turn open a whole new perspective on possible disease/sex-specific biomarkers.

"The lack of funding in women's health is why, even today, we still don't have answers about so much of the basic physiology of 50% of the world's population. For example, did you know that there are approximately 400 studies on menstrual effluent compared with 15'000 studies on semen? Or that in 2020, only 10.7% of the basic scientific research funding provided by the United States government went towards women's health research? The lack of funding in women's health has dire real-world consequences. If stories form a backbone for our society — how can we weave stories that incentivise – no, demands — innovation in women's health? It requires a movement — and that movement starts with us."

Oriana Kraft
Founder, FemTechnology

In recent years, the field of personalized medicine and drug development has boomed, leading to higher Probability of Success (PoS) and blockbuster drugs. While identifying biomarkers can pose challenges, in this context, the most evident biomarker is biological sex. Quoting Dr. Marcus Altfeld, an immunologist at the Heinrich Pette Institute in Hamburg, Germany, "*Everyone is speaking about personalized medicine, having personalized approaches for every*

individual (…) I think having a step before there, maybe stratifying the population into male and female, and optimizing treatment strategies there, is an important step."[7]. By recognizing the significance of biological sex as a logical biomarker in drug development, we can pave the way for tailored therapies that cater to the specific needs of female (and male) patients, ultimately leading to higher treatment efficacy and a greater PoS for drug developers. This approach also opens up the possibility of repurposing and tapping into previously unexplored diseases, as many drugs may have potential when tested separately in both sexes.

The opportunities for better diagnostic and therapeutic solutions in Women's Health are vast. For instance, understanding endometriosis better could lead to targeted solutions that replace invasive procedures like laparoscopies and hysterectomies, reducing the economic strain and enhancing the quality of life for patients and their families.

Liliane Brunner Halbach
Artemis Women's Health Foundation
Deputy Head Therapy Development Accelerator at the University of Zurich

Roots of Disparity: Funding and R&D Challenges

Women's Health has been historically underfunded[1,3] which has hindered innovation greatly both in diagnosis and treatment. This critical imbalance persists despite the widespread prevalence of conditions such as endometriosis, which afflicts an astonishing 10% of females worldwide, and represents a pressing need for more effective diagnostic and treatment options[6].

A stark disparity becomes evident when comparing Women's Health to other therapeutic areas within the biopharmaceutical industry. The market is dominated by generics, primarily hormone-targeting drugs, leading to fierce pricing competition. Additionally, regulatory guidance from FDA and EMA on several of these conditions remains conspicuously absent contributing to the already high R&D hurdles for clinical trial sponsors (e.g., lack of clinical trial endpoints, low recruitment rates, inadequate animal models). Furthermore, there is a profound lack of comprehension surrounding the underlying pathophysiology of these diseases, a deficiency in

basic research that significantly constrains the development of novel mechanisms of action and/or bringing innovative treatments from other therapeutic areas into Women's Health. Nevertheless, there is a growing number of initiatives aimed at supporting early-stage innovative developments. One example of a funding model that encourages transformative research is the *BioInnovation Institute (BII)*. BII provides financial support for innovations that propel the creation of novel solutions, particularly by early-stage life science start-ups operating in diverse areas, including Women's Health. Another example is *Repro Grants*, which is a program that awards grants to scientists or academic institutions dedicated to the advancement of Women's Health research. While these initiatives undeniably play a pivotal role in propelling early-stage research aimed at unraveling the underlying pathophysiology of diseases, it is imperative to acknowledge that realizing substantial progress in this field will necessitate significantly larger investments.

3. Way forward to Financing Innovation in Women's Health

Irrespective of the therapeutic area, to increase interest of investors, pharmaceutical industry and other stakeholders, a positive business case needs to be established. In the context of Women's Health, which impacts over half of the global population, it is crucial to articulate both the broader economic rationale at the government level and the more focused investment perspective relevant to private investors with shorter timeframes. At the governmental level, the 2021 Women's Health Access Matters (WHAM) report already demonstrated that funding Women's Health research can have a great economic impact (investing $300 million can save $13 billion to the US economy in the next 13 to 25 years)[2]. Regarding private investors, one could also argue that the current model of Venture Capital investment in biopharma may not be adapted to the field of Women's Health since VC incentives focus on the "*sprint*" commercialization, rather than the "*marathon*" of creating value and change. Changing such dynamic is a much broader Therapeutic Area-agnostic endeavor.

Investment in women's health will accelerate the transformation of dreams into innovation reality.

Kathrin Schoenborn
Advisor | Business Angel | Non-executive Director | Diversity enthusiast

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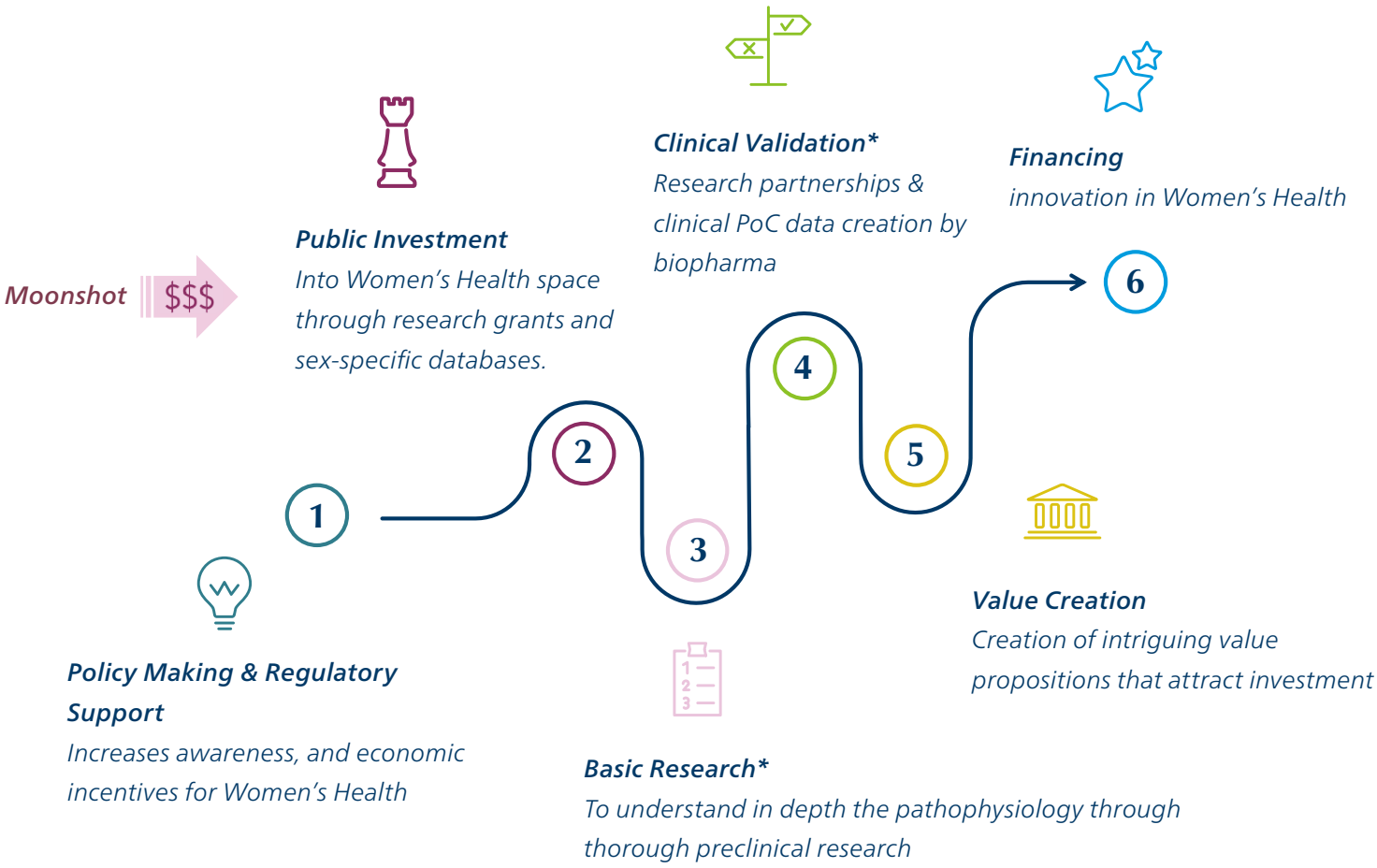

***Figure 1** | Achieving the goal of financing innovation in Women's Health starting from a moonshot investment in research or, in the absence of it, from effective policy making & regulatory support. *some solutions may enter this path at a later stage if the field is able to leverage currently available sex data; Source: Catenion*

In the current financing setup, when economic incentives for biopharma are lacking, it becomes necessary to establish new ones. There are two main paths to create such incentives. One possible path is to launch a Women's Health moonshot initiative with substantial grants for both basic and clinical research, including sex-specific biomarker discovery thus de-risking private investment. However, in the absence of such substantial investment, the foundational step should involve Policy Making & Regulatory support.

In Figure 1, we present this potential pathway to achieve financing innovation in Women's Health. Once a foundation of Policy Making & Regulatory Support and/or sufficient public investment is in place, the next step is to build a solid foundation of basic research. Thorough preclinical studies are essential, allowing us to better understand pathophysiology, a vital

component on our journey toward financing innovation. Clinical Proof of Concept (PoC) takes the stage next (Step 4). This phase relies on research partnerships and the generation of clinical PoC data by biopharma to create compelling value propositions (Step 5) that can attract the investment needed to drive innovation in Women's Health (Step 6). It is important to recognize that this journey towards financing innovation in Women's Health will not be a swift one, as basic research, for example, cannot yield immediate results and requires significant time and effort – a reality that may currently pose challenges to venture capital timelines that prioritize rapid PoC and quick exits.

4. Drawing Parallels with Orphan Drug Development:

Women's Health would not be the first example of policy making and regulatory change driving innovation. Historically, orphan diseases were an area in which for many years biotechnology and pharmaceutical companies refrained from developing drugs due to low expected commercial returns. This changed upon the efforts of patient organizations that led to the Orphan Drug Act (Figure 2)[4,5]. Learning from the success of the Orphan Drug Act, which transformed rare disease research, we can apply similar principles to Women's Health. Policy makers, regulators, patient organizations, and public funding agencies played a pivotal role in incentivizing drug development for rare diseases. A positive business case was created by addressing pricing issues, encouraging investment, and improving patient access. Similarly, for Women's Health, a collaborative effort is necessary to encourage investment and research to initiate the steps towards investment in the field.

The same is true for other fields such as Pediatrics, in which there are clear differences in responses to drugs between children and adults, including different dosages and unique pediatric adverse events. Therefore the Best Pharmaceuticals for Children Act (BPCA) in 2002 and the Pediatric Research Equity Act (PREA) in 2003, driven by the United States Congress, were established for similar reasons that we observe for females today: safety and effectiveness differences (out of the 668 drugs used for the 20 most frequent treatment regimens in the US, 86 show significant sex differences in pharmacokinetics in females[8]). Even cases that are also far from being addressed, such as Racial and Ethical Representation in clinical trials, had legislative acts by the FDA (FDA Amendments Act of 2007 (FDAAA), Prescription Drug User Fee Act (PDUFA) 2016, 2021 FDA's guidance on Enhancing the Diversity of Clinical Trial Populations) in order to encourage development of drugs that address health disparities. These health disparities

are also true for females who are underrepresented in preclinical studies & clinical trials. (e.g., Cardiovascular Diseases are the #1 reason of death in females, but in clinical trials, only a quarter of participants are females[9]).

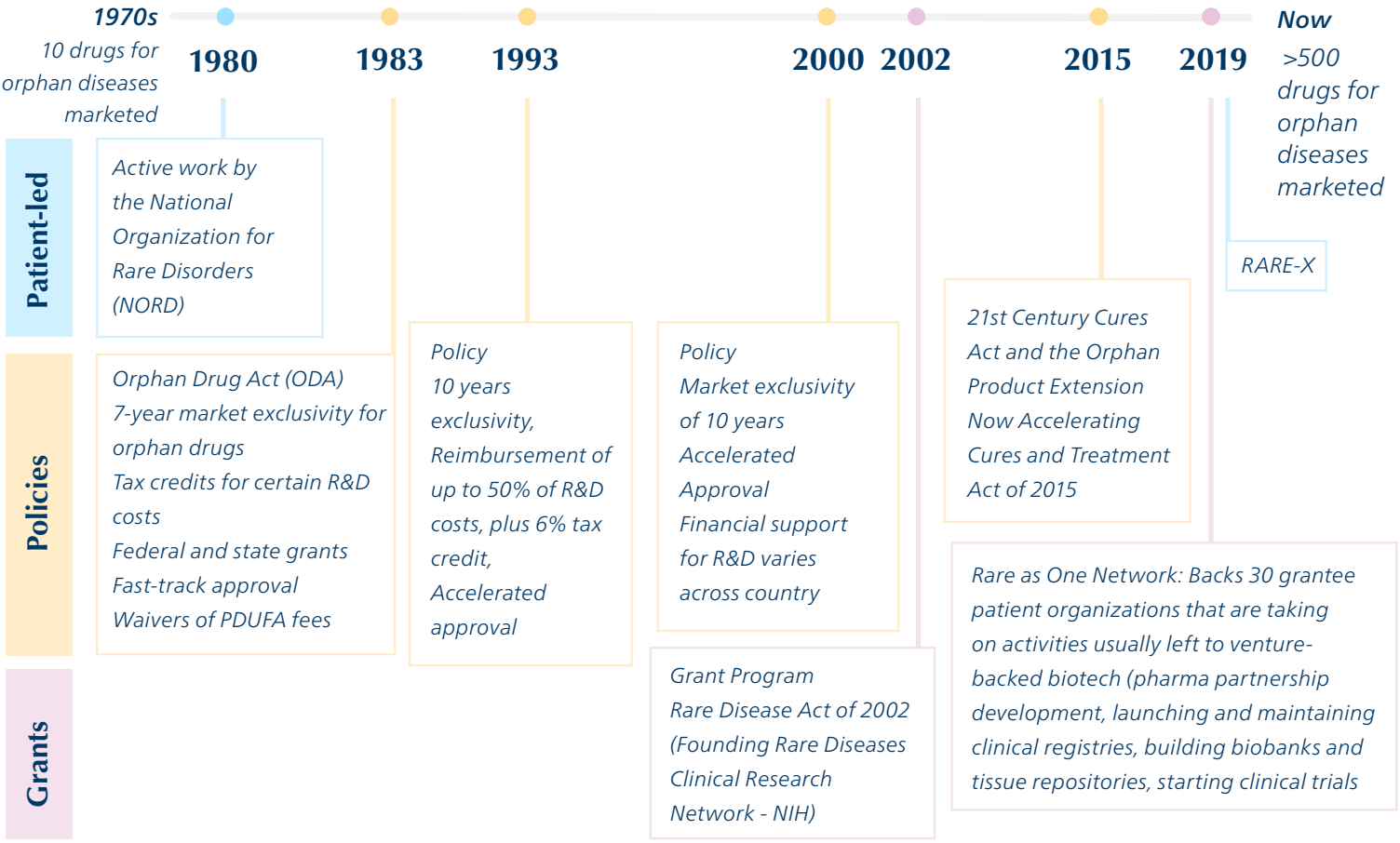

Figure 2 | *Orphan Drugs: From empty pipelines to >500 drugs marketed. Sources: Catenion analysis; FDA.gov; NORD "Impact of the Orphan Drug Tax Credit on treatments for rare diseases" 2015*

5. Policy Making for Women's Health Innovation:

Given the importance of policy making to drive innovation forward and increase financial incentives to the Women's Health field, Catenion discussed the current state of the Women's Health with 3 experts from United States (US) and 2 from Europe (EU) (policy maker experts from EU and US, and pharmaceutical, medical device and regulatory experts from the EMA and FDA).

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Across the spectrum of experts, a consensus emerges highlighting low awareness and limited interest in the Women's Health arena. However, there are differences in sentiment when contemplating the trajectory of this field over the next 5 to 10 years. While a majority of experts exhibit optimism by anticipating the formulation and implementation of policies aimed at fostering innovation in Women's Health within the next 5 years, and quite possibly extending into the subsequent decade, it is worth noting that some remain cautiously skeptical about the likelihood of substantial transformation during this period. All experts concur that ongoing discussions about reproductive rights have heightened interest in Women's Health as a field. However, the challenge of expanding beyond this narrow definition of Women's Health remains substantial. Notably, some experts believe that as a new generation of policymakers assumes positions of influence and leadership teams in regulatory bodies undergo changes, their unique experiences and insights into the healthcare system will bring about different expectations and catalyze change within the field.

"... we are playing catchup up. Not only do we have to create knowledge for the future, we actually have to create awareness and advocacy for right now to continue to make sure that dollars get channeled into the women's health category."

Michael Annichine
CEO Magee-Womens Research Institute and Foundation

Education of the General Public and Policy Makers is Vital to Raise Awareness and Interest in innovation for Women's Health

Women's Health currently receives insufficient recognition from both policymakers and regulators. This is evident in the inadequate funding allocated to researchers and entrepreneurs in the field, resulting in a limited understanding of the underlying pathophysiological processes of related diseases. As elaborated earlier, there's a pressing need for increased incentives on the regulatory front, similar to those granted to orphan diseases. While the FDA and EMA review and approve novel pharmaceuticals and medical devices, these agencies function solely as regulatory bodies, adhering to decisions made by healthcare policymakers (the US congress and the European Commission, respectively). Although they consult policy making, they lack the autonomy to offer incentives independently.

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Therefore, it becomes imperative to raise policymakers' awareness about the current state of Women's Health and the areas that require enhancement.

One of the primary policy challenges encountered is the lack of a comprehensive understanding of Women's Health. Today, many policymakers and policies in this domain narrowly focus on reproductive health. As voiced by an interviewed US policymaking expert, "*…the important thing is going to be trying to point out that there's a lot more to Women's Health… All their [policymakers'] focus is on access to abortion and domestic violence and that's it. There is more to Women's Health than just pregnancy. There's a way to leverage concern over reproductive health. But to point out that reproductive health is just a small part of the unique needs of women.*".

Empowering women's health innovation is not just a choice; it's a responsibility we all share. Let's invest in a healthier and equal future.

Cristina Vilarmau
Innovation Manager MiMARK

To alter this narrative effectively, establishing a solid business case for Women's Health is critical. This entails identifying all needs, including but not limited to reproductive health, quantifying their impact on healthcare costs, and showcasing how resolving these issues can lead to long-term healthcare cost savings. Only then advocating rooted in data for policy changes can be done. In recent years there have been noticeable shifts in the field. In addition to WHAM's efforts to highlight the economic aspects of investing in Women's Health, ongoing initiatives led by the NHS Confederation in England are working on a report to highlight the business case of investing in Women's Health. This report will quantify the intrinsic links between investment in women's health and wider economic growth to make the case to the UK government that women's health, the NHS, and the wider economy cannot continue to be viewed as separate concerns, and the most basic needs of 51% of the population should be prioritized.

The Pivotal Role of Patient Advocacy Groups in Shaping Policy

Experts unanimously affirmed the pivotal role of effective policymaking in driving incentives

within the Women's Health field. To engage policymakers effectively, experts stressed the significance of leveraging patient advocacy groups and the influence these groups can exert. To ensure productive discussions with tangible outcomes, it is vital to approach policymakers with specific indications that exhibit high unmet medical needs, rather than approaching Women's Health as an entity. Supporting these discussions with patient stories and empirical data, demonstrating unmet medical needs and the economic benefits of improving current treatment options is imperative. For instance, highlighting the needs of the growing number of women entering menopause with limited options to enhance their quality of life, which can result in prolonged participation in the workforce. A recent study by Mayo Clinic supported this by showcasing that menopausal symptoms cost American women an estimated $1.8 billion in lost working time per year[10].

Leveraging Established Consortia to Enhance Credibility

While patient advocacy groups provide essential real-world examples of the impact of diseases on individuals, they require scientific validation from the industry. To accomplish this effectively, experts emphasize the importance of establishing consortia that bring together researchers, drug developers, and physicians to address critical gaps and define objectives aimed at resolving these issues. Given that approximately 80% of healthcare professionals in the US & EU are female[11,12], it is reasonable to assume that the industry would be keen to form such consortia. While newly formed consortia, particularly those focused on specific Women's Health indications, are crucial in the field, enhancing the credibility of discussions with policymakers may necessitate engaging with more established consortia such as The American College of Obstetricians and Gynecologists (ACOG) or The European Board & College Of Obstetrics And Gynecology (EBCOG).

6. Supporting Innovation in Women's Health – a Roadmap:

Based on the research and perspectives by Catenion, insightful discussions held during the *FemTechnology* Summit workshop "Financing Innovation in Women's Health" with various industry stakeholders, and in-depth interviews with policy makers and regulatory experts, a roadmap has been put together. The goal of this roadmap is to serve as a valuable guide to steer efforts and as a foundation for discussions regarding the necessary actions to be taken in both the short term and as we shape our long-term strategies.

01

Short-term (~2y)

Identify successful companies and indications with high unmet medical need in Women's Health through systematic assessment, **triggering enthusiasm and interest**. This would allow the field to be portrayed as a successful business case. Start **engaging with regulators and policy makers** to develop mid and long term goals.

02

Mid-term (~4y)

Develop a **health economics model** to **demonstrate the positive business case** for investing in Women's Health, supporting funding decisions using two perspectives:

- → Business Case for governmental entities (mostly in US and EU) focusing on return on investing in Women's Health research by healthcare savings and economic gains (e.g., working days gained). An example is the current effort by the NHS Confederation for England's Women Health initiative (more info in the next section). This effort requires a concerted approach and an injection of substantial capital into Women's Health (such as the *NIH Cancer moonshot* which authorized $1.8bn to cancer research over a 7 year period);
- → Business Case for private investors focusing on return on investment for Women's Health, emphasizing the potential return on investment and the reduced risk associated with this therapeutic area when substantial government backing mirror practices in other domains.

03

Long-term (~7y)

a) Break the silos through a collaborative effort to direct existing and further funding, bridging gaps between basic and applied research in Women's Health. Such consortia should involve not only pharmaceutical

industry by also patient advocacy groups, regulators, policy makers, researchers, translational scientists, etc.

b) Regulatory Incentives: Advocate for regulatory incentives through established consortia to promote development and innovation, learning from successful models in other therapeutic areas (e.g., orphan drugs and pediatrics). Engage in education efforts of regulators regarding the key challenges of drug developers in the field of Women's Health and how a reward based incentive (e.g., longer exclusivity, accelerated development path,) could lead to more innovation for these patients with high unmet medical needs.

7. Call to Action

To follow this roadmap, different actionable strategies can be applied. The recent report by the Bill & Melinda Gates Foundation and the US National Institutes of Health (NIH) provides a complementary perspective by outlining ten specific focus areas with detailed actions for an equitable inclusion, participation, and funding of Women's Health innovation.13 The relevance of these strategies, both presented here and in other sources, can differ based on your role and perspective as a reader. Whether you are a patient, a Woman's Health founder, a pharmaceutical executive, a medical doctor, a politician, a health economist, or simply an engaged citizen who values equitable healthcare, these approaches offer various ways for you to get involved and make a positive impact.

It is evident that a collaborative effort is essential to construct a compelling business case for governmental entities to fund Women's Health and help de-risk investment for private investors. To this end, we invite you to consider engaging with and supporting this field as it moves forward.

Below, we enumerate various strategies in which you can actively participate:

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- ***Educate and Raise Awareness***
  Launch targeted awareness campaigns, raise your voice on social media to shed light on the wide-ranging health needs of women that go beyond reproductive issues. Share information, stories, and statistics on the existing gaps and challenges in Women's Health (e.g., *XProject from Roche*, *FemTechnology*). As professionals within healthcare organizations, advocate internally for a stronger commitment to research and investment in areas pertinent to Women's Health from an R&D perspective (e.g., The Wyss Institute's Women's Health Catalyst at Harvard University).

- ***Empower Patient Advocacy***
  Collaborate with patient advocacy groups, participate if you are a patient, or initiate one if needed. Share real-life stories and empirical data that illustrate the unmet medical needs in Women's Health, emphasizing the profound impact on women's lives and the economy (e.g., *The National Polycystic Ovary Syndrome Association*, *The Endometriosis Association*, *The Endometriosis Foundation of America*). Help policymakers and politicians understand the urgency of these issues.

- ***Build Credibility Through Collaborations***
  There is a need for diverse perspectives and interdisciplinary collaboration in Women's Health innovation. Discuss and collaborate with healthcare professionals, researchers, tech experts, entrepreneurs, etc. to foster more comprehensive solutions. Engage with established organizations such as ACOG and EBCOG to enhance credibility when advocating for policy changes (e.g., *The Lancet Commission on Women, Power and Cancer*).

- ***Establish a Business Case for Women's Health***
  Support organizations and initiatives dedicated to crafting a compelling business case that attracts investment. An excellent illustration of this approach is the "*Women's Health Access Matters*" initiative in the United States. Similarly, in England, the NHS Confederation Initiative is aiming to demonstrate the economic benefits of investing in Women's Health to not only advance the country's Women's Health strategy and secure sustainable funding but also to highlight the broader value of investment beyond the NHS (reach out to *Bridget Gorham* for more information). If you are in a position to contribute to

these initiatives, you can do so by donating or by actively participating in the creation and provision of the data required.

- ***Participate in Clinical Trials***
  If you are eligible and interested, consider participating in clinical trials related to Women's Health. The involvement can contribute to vital research and will also provide valuable data that can drive innovation.

- ***Support Nonprofits and Research Organizations***
  Numerous nonprofit organizations and research institutes are dedicated to advancing Women's Health (e.g., *Women's Health Access Matters - WHAM*, *Society for Women's Health Research - SWHR*). Consider donating to these organizations, participating in their events, or volunteering.

"These can feel like overwhelming challenges but I get excited about it because you can actually go out in the world and see some really exciting things that are happening on the ground and you know there's the potential to make this look very different. In the same way that many of these things have changed in our lifetimes, my hope is that still in our lifetime we'll see more change happen. (...) Given the amount of treatments that we (Roche) have that can actually impact women's health, I believe we have a very unique, important and urgent role to play in getting this dialogue about women's health more out there."

Teresa Graham
CEO Roche Pharmaceuticals

- ***Advocate for Regulatory Support & Engage with Policy Makers***
  Use your voice to advocate for regulatory incentives similar to those granted to orphan diseases, for example. These incentives can kickstart much-needed research and innovation in Women's Health. Write letters, make phone calls, or meet with local representatives to emphasize the significance of Women's Health and the need for financial support. Or, if you can, collaborate with regulatory agencies such as the

FDA and EMA to highlight the unique challenges and opportunities within this field, by discussing some of the following points:

- → Mandatory public reporting of preclinical and clinical trials results segregated by sex
- → Increase funding for basic research and for biobanks with segregated data by sex
- → Simplified FDA/EMA submissions (develop as the example from ODA)
- → Expedite pathways for innovative treatments and diagnostics in Women's Health
- → Extended patent life for products launched in highly genericized indications with no innovation in the last 10 years and high unmet medical need

- ***Showcase Success and Solutions***
  Highlight successful Women's Health initiatives and innovations that have effectively addressed unmet medical needs.

Geographical Implications:

While the focus of this report predominantly centers on innovation in women's health within the United States and the United Kingdom, it is worth noting the potential significance of this geographical emphasis. One could speculate that these countries are featured prominently due to their more advanced policies and research environments pertaining to women's health. Nevertheless, it raises an intriguing point about the potential for Europe to become a pioneering force in this domain. With increasing politicization of women's health and reproductive rights in the United States, an opportunity may exist for Europe to establish itself as a cutting-edge hub for innovation in women's health. If Europe or other regions, like Asia, were to implement attractive policies and incentives, they could position themselves as frontrunners in this critical field, ultimately fostering positive global impact.

8. Conclusion

The path to financing innovation in Women's Health requires a strategic and concerted effort driven by policy making, public investment, and collaboration. Drawing from successful models and supported by a compelling business case to attract investment to R&D, access to effective treatments in Women's Health can be created. However, it is important to acknowledge that venturing beyond the scope of reproductive health will require a longer and more challenging journey. Overall, financing innovation in Women's Health is an imperative for improving the well-being of females worldwide as well as a strategic opportunity for the pharmaceutical industry to develop novel solutions and address dire unmet medical needs.

Any market-player who ignores the needs of women will be losing out.

Stephanie Sassman

Portfolio Leader Women's Health at Roche

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Catenion is a management consulting firm devoted to helping pharmaceutical and biotech companies implement more innovative and effective strategies. Catenion works across multiple therapeutic areas for the global biopharma industry including Women's Health.

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In Partnership with

Sources

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