Conference Report

Summary Report on Innovative Approaches to Enhance Patient Care in Women's Health

Summary Of

The ESHRE 39th Annual Meeting

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July 2023

ESHRE serves as a platform for reproductive medicine conferences, featuring sessions that emphasize the need for research to explore innovative approaches to enhance patient care in women's health

Context

The 39th annual meeting of the European Society of Human Reproduction and Embryology (ESHRE) took place in Copenhagen, Denmark from June 25th to 28th 2023

ESHRE's primary objective is to foster interest in and enhance comprehension of reproductive biology and medicine.

Scope of Discussion

The report offers a glimpse into a few case studies of scientific programs conducted on the theme of innovative approaches to enhance patient care.

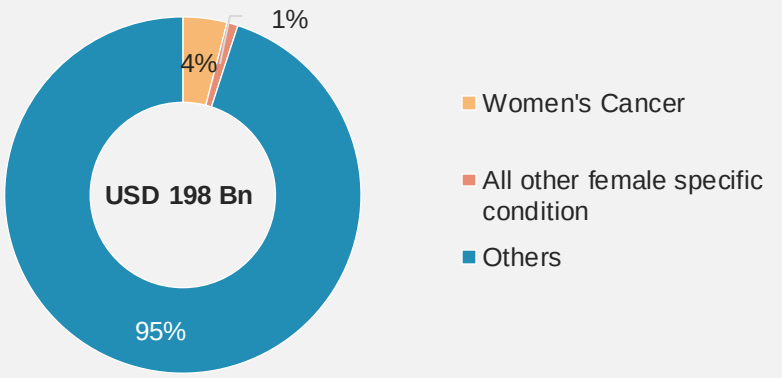
Session Themes:

- Revolutionizing Reproductive Health: Microbiome-based Innovations
- Impact of Microbiome Transplantation on Reproductive Outcomes
- Evolving to Enhance Patient Care: Follitropin Delta in Diverse Populations and Clinical Settings

Insufficient representation of women in clinical trials has led to a significant delay in women's health research, resulting in unmet needs in female-specific diseases and increasing costs

Overview

R&D Spend Biopharma (2020)



~1%

Of healthcare research and innovation is invested in female-specific conditions apart from oncology.

Without substantial investment in biomedical innovation in women's health, this gender gap would continue to grow.

- Women were not required to be included in clinical trial research in the US until 1993 (NIH Revitalization Act).
- Insufficient representation of women in clinical trials, along with limited investment and research (1% of healthcare research is invested in female-specific conditions besides oncology) has resulted in a five-decade lag in women's health research.
- This contributes to unmet needs in female-specific diseases, including the rising costs associated with declining fertility rates and increasing maternity complications.
- With the advent of antibiotic resistance, new therapies are being explored for reproductive health. A new class of drugs, microbiome therapeutics, is gaining prominence.
  - Microbiome-based therapeutics seek to restore the healthy microbial populations that reside on or within the host and the downstream metabolic networks that the microbiome directs.

Source: *ESHRE 39th Annual Meeting*

The speaker emphasized the exploration of microbiome therapy as an alternative intervention to restore microbial balance and treat dysbiosis, characterized by an imbalance in the microbial community

Case Study 1 (1/2) – Revolutionizing Reproductive Health: Microbiome-based Innovations

Dysbiosis

- Infertility
- Repeated Implantation Failure
- Recurrent Pregnancy Loss
- Prebirth Term
- Endometriosis
- Chronic Endometritis
- Bacterial Vaginosis
- Pelvic Inflammatory Diseases

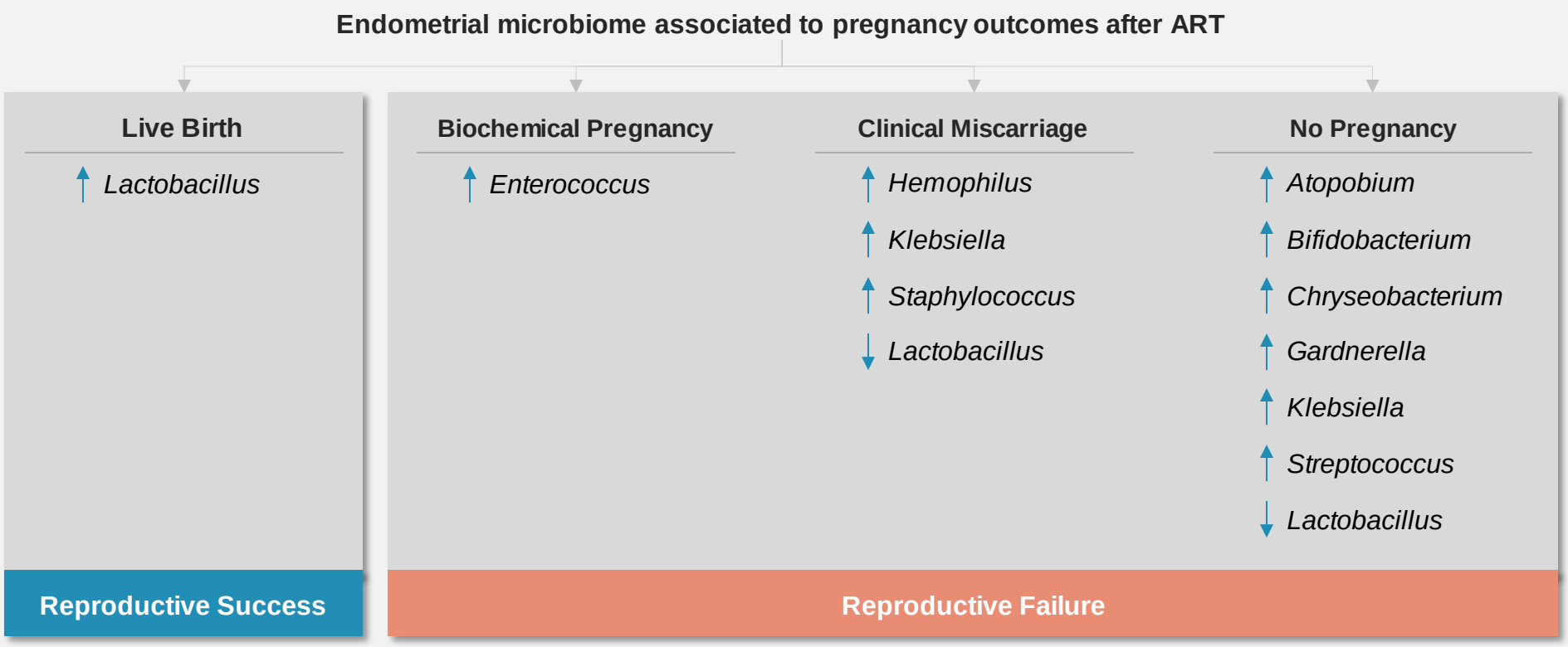
- Reproductive tract dysbiosis leads to infertility, repeated implantation failure, preterm loss, endometriosis, and other related conditions.
- Microbiome therapy offers a promising solution to address this issue by restoring microbial balance.
- A collaborative study with Ferring focused on understanding the mechanisms of pathogen-endometrial host interaction in patients with reproductive failure using advanced sequencing techniques.
- The following results were found:
  - The presence of bacterial pathogens in the endometrial fluid is significantly linked to reproductive failures.
  - Patients experiencing reproductive failures exhibit dysregulation in GPCR signaling pathways, which are targeted by ~35% of prescription drugs.
  - Therefore, it is essential to reconsider the choice between bacteria (e.g., microbiome therapy) and pharmaceutical interventions when devising strategies to manipulate GPCR signaling in the endometrium.

Source: *ESHRE 39th Annual Meeting*

Reproductive success has been demonstrated to be associated with high lactobacillus presence, while reproductive failure is characterized by reduced lactobacillus and increased dysbiotic bacteria

Case Study 1 (2/2) – Revolutionizing Reproductive Health: Microbiome-based Innovations

Results of a study carried out on infertile patients: Impact of endometrial microbiome on reproductive outcomes



Endometrial microbiota composition is associated with reproductive outcome in infertile patients

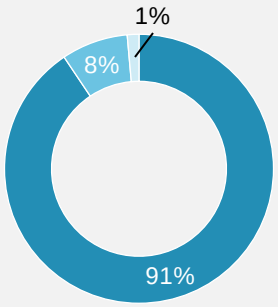
Source: *ESHRE 39th Annual Meeting*

Another study presented focused on the effectiveness of vaginal microbiome transplantation as a potential approach for treating dysbiosis, despite being in its early stages of development

Case Study 2 (1/2) – Impact of Microbiome Transplantation on Reproductive Outcomes

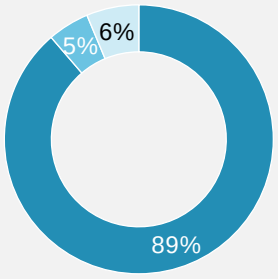
Endometrial microbiota composition of a patient with dysbiosis and a healthy microbiome donor

26 days pre VMT



A dysbiosis patient's microbiome was exclusively dominated by Gardnerella vaginalis.

Donor Microbiome



A healthy microbiome donor was selected that had a dominance of lactobacillus crispatus.

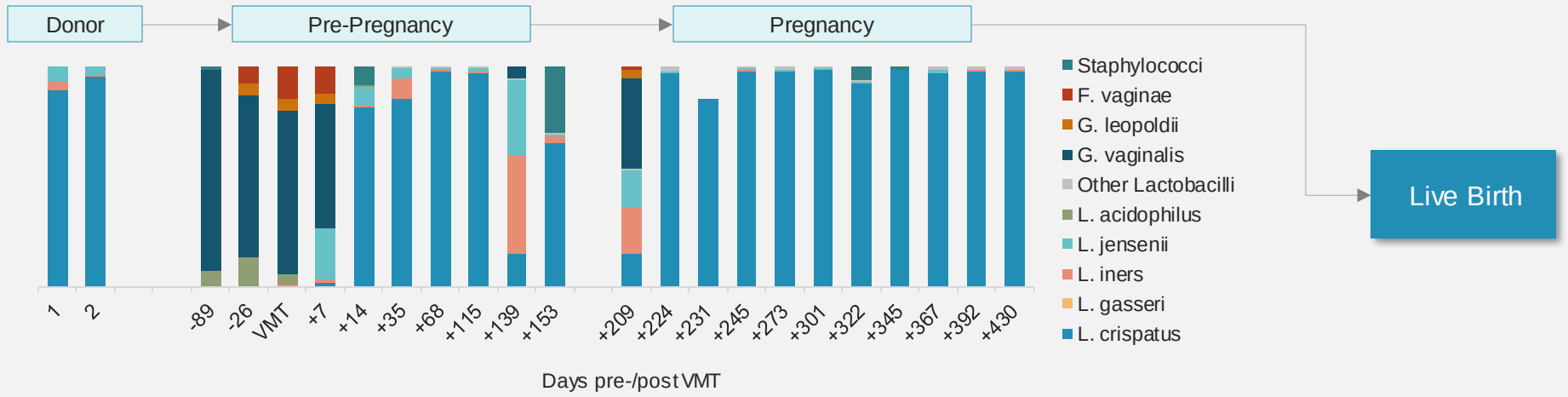
- Vaginal microbiome transplantation (VMT) is a promising treatment that involves transferring healthy vaginal microbiota from a donor to restore normal microbial composition in diseased patients.
- VMT is a potential treatment for reproductive tract dysbiosis, and the collaborative efforts of corporations and academia have significantly advanced the understanding of the microbiome in relation to women's health and diseases, leading to further insights.
- Studies demonstrated the effectiveness of VMT in treating dysbiosis, with successful pregnancy outcomes observed as a result of decreased presence of Gardnerella vaginalis and the dominance of lactobacillus in the transplanted microbiome.

Source: *ESHRE 39th Annual Meeting*

The study results demonstrated the success of VMT in treating dysbiosis and improving pregnancy outcomes

Case Study 2 (2/2) – Impact of Microbiome Transplantation on Reproductive Outcomes

VMT in dysbiosis patient



- The VMT study shows the following findings:
  - Prior to undergoing VMT, the initial three samples indicated a prevalence of Gardnerella. Following one week after VMT, the patient exhibited no dysbiosis symptoms primarily due to a slight increase in lactobacillus.
  - Once the patient became pregnant, the first sample once again revealed Gardnerella dominance, prompting a second transplantation from the same donor. After the second VMT, the patient reverted to a microbiome dominated by lactobacillus.
  - Ultimately, the patient achieved a successful delivery of a healthy baby.

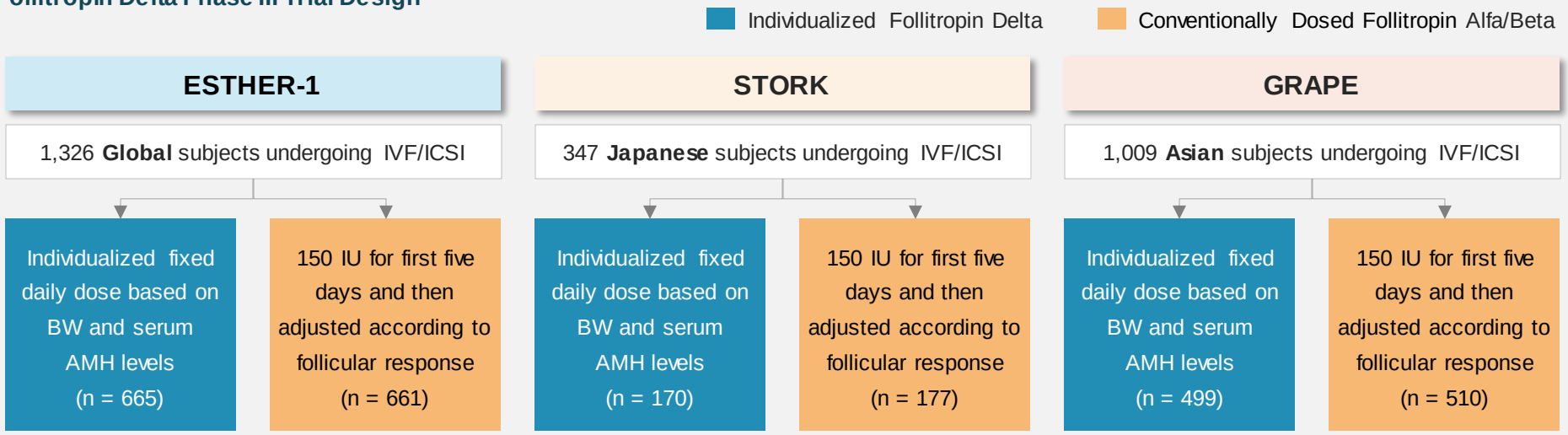
Source: *ESHRE 39th Annual Meeting*

The last session focused on presenting new data supporting the use of follitropin delta for individualized fertility treatment

Case Study 3 (1/3) – Evolution to Enhance Patient Care: Follitropin Delta in Diverse Population and Clinical Settings

- Follitropin delta, a human cell-derived recombinant follicle-stimulating hormone (rFSH), offers a superior ovarian response compared to follitropin alfa, with a consistent PK profile across diverse ethnicities.
- A tailored dosing of Follitropin delta is made possible through an AI algorithm utilizing body weight (BW) and anti-Mullerian hormone (AMH) levels.
- Phase III trials involving multiple ethnicities demonstrated high live birth rates and reduced incidents of early ovarian hyperstimulation syndrome (OHSS) with Follitropin delta. Notably, subjects with high AMH levels achieved higher live birth rates.
- With registrations in 75 countries, Follitropin delta caters to various patient types and treatment scenarios, representing an innovative advancement in individualized treatment approaches.

Follitropin Delta Phase III Trial Design



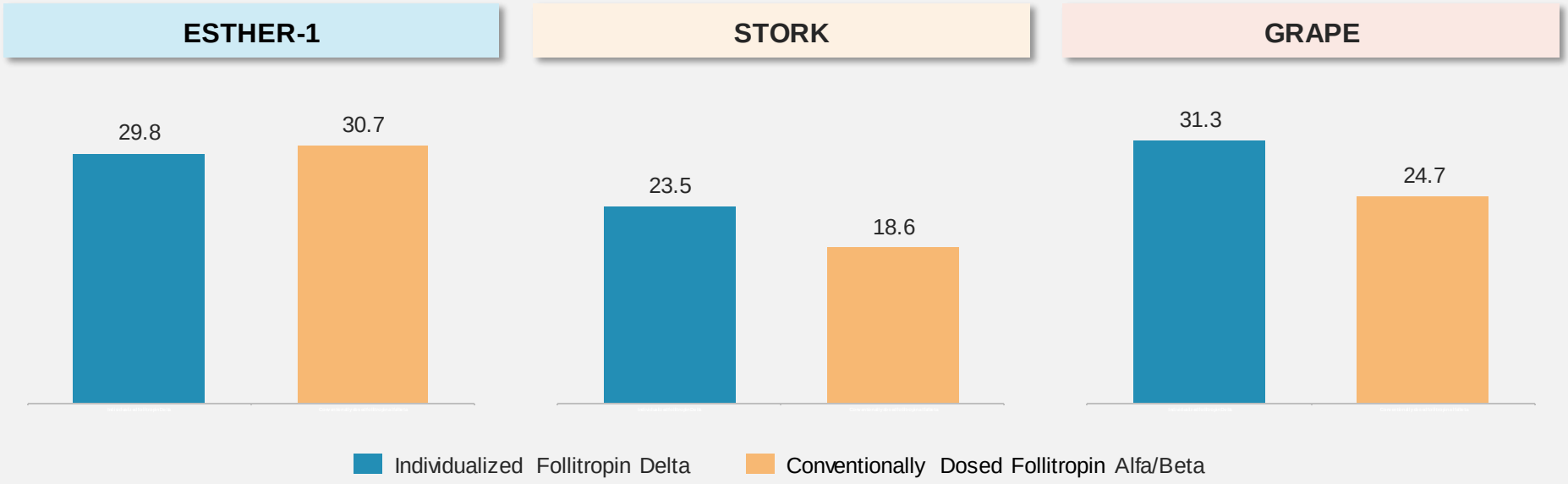
Source: *ESHRE 39th Annual Meeting*

Significant higher live birth rates have been achieved between groups with individualized follitropin delta dosing vs conventional follitropin alfa/beta dosing in Asian population study (GRAPE)

Case Study 3 (2/3) – Evolution to Enhance Patient Care: Follitropin Delta in Diverse Population and Clinical Settings

Live birth rate of patients administered with individualized follitropin delta vs conventionally dosed follitropin alfa/beta

Consistent live birth rate was achieved with follitropin delta in all three trials



ESTHER-1	STORK	GRAPE
Comparable live birth rate between groups	Comparable live birth rate between groups	Significantly higher live birth rate with individualized follitropin delta vs alfa

Source: *ESHRE 39th Annual Meeting*

The session concluded by emphasizing the effectiveness of individualized follitropin delta, resulting in comparable dosing, a higher rate of live births, and a decreased risk of OHSS

Case Study 3 (3/3) – Evolution to Enhance Patient Care: Follitropin Delta in Diverse Population and Clinical Settings

The session concluded with emphasis on the following four points:

Comparable pregnancy rates by individualized follitropin delta and conventional follitropin alfa	▪ The study showed that tailoring the dosage of follitropin delta to individual patients yielded comparable ongoing pregnancy rates when compared to conventional dosing with follitropin alfa in a diverse Asian population.
Higher live birth rate with individualized follitropin delta	▪ Supplementary data on predefined secondary outcomes demonstrated that personalized dosing with Rekovelle led to a significant increase in live birth rates among normal and high responders.
Reduced risk of ovarian hyperstimulation syndrome (OHSS) with individualized follitropin delta	▪ The findings indicated that using the personalized dosing regimen of Rekovelle for ovarian stimulation effectively reduced the risk of OHSS without compromising its efficacy.

Source: *ESHRE 39th Annual Meeting*

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