

PRGLAC

Small Industry Perspective

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LeKeisha, living with epilepsy



Inspired by **patients.**
Driven by **science.**

Perspective of Small Industry



Healthcare Ecosystem and the Role of UCB to Inspire Patients and Drive Science



UCB Commitment to Patients



Programs to Advance Research and Outcomes Specific to Pregnant and Lactating Women

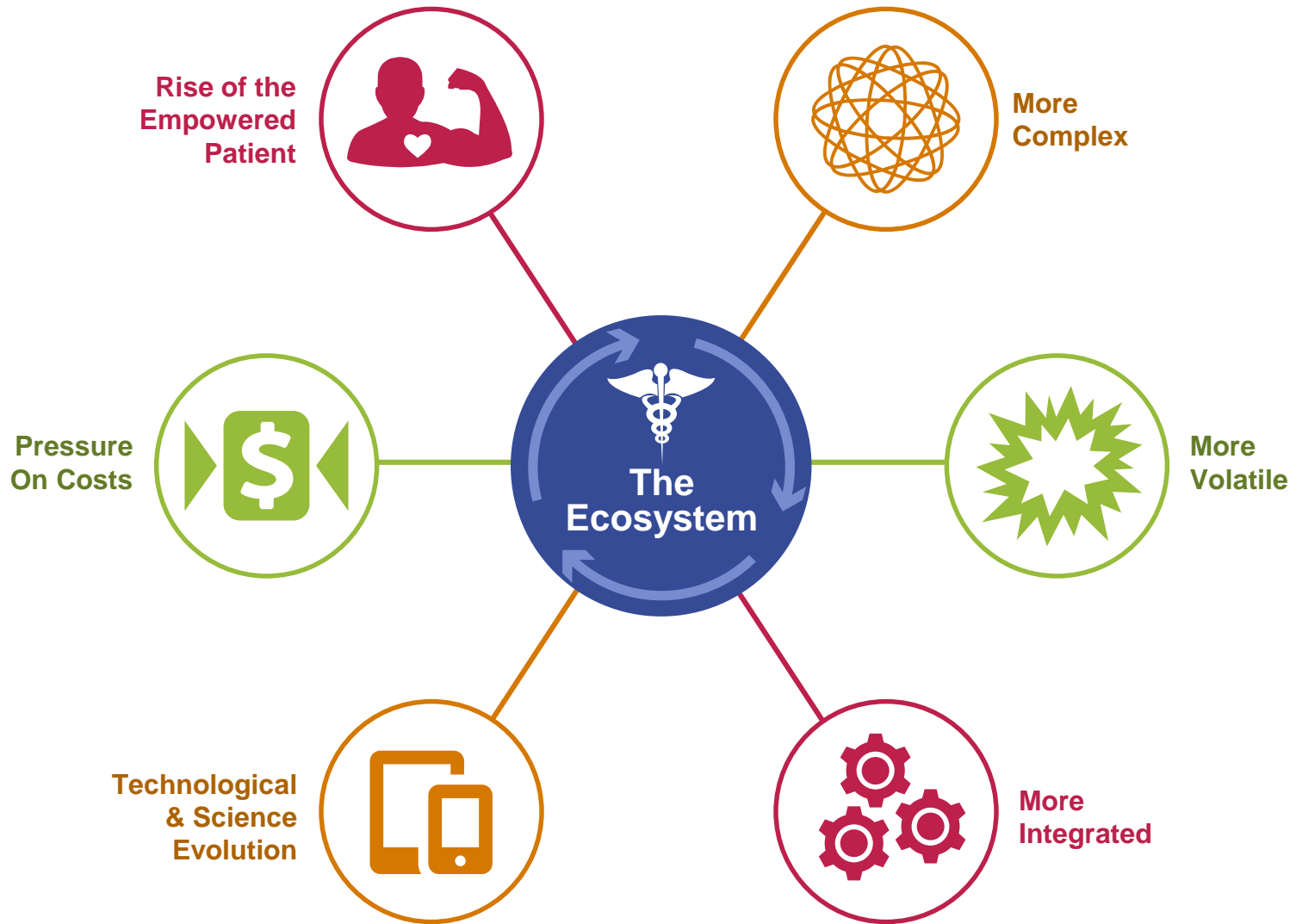


Small Industry Recommendations

Healthcare Ecosystem and the Role of UCB to Inspire Patients and Drive Science



What does the Healthcare Ecosystem look like?



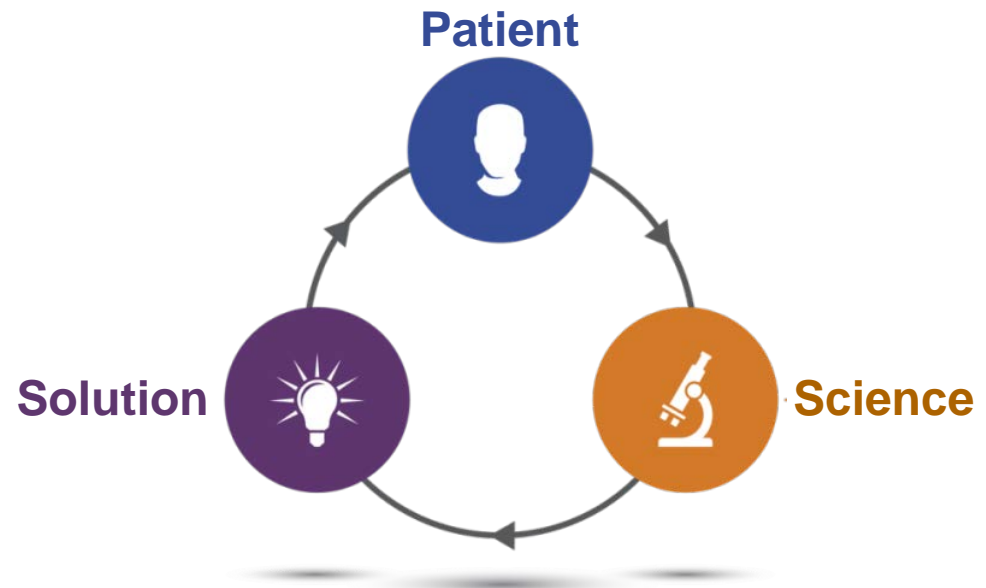
UCB – Inspired by patients. Driven by science.

We are a global biopharmaceutical company focused on delivering innovative solutions that ensure the right medicines and care reach patients living with severe diseases

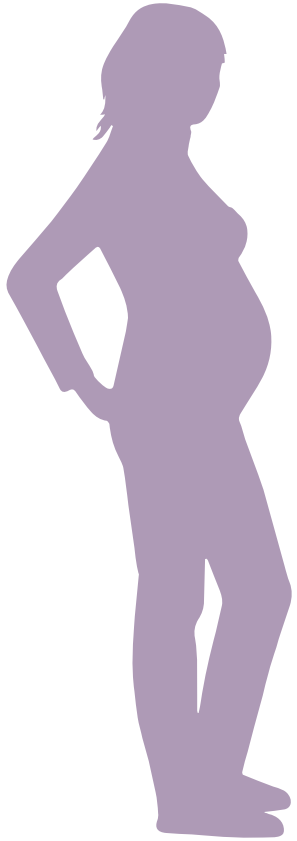
Our Purpose Creating value for patients

Everything we do starts with one simple question:

“How do we create more value for people living with severe diseases?”



The Lived Experience



“ Then I think what if ... I tell him and we stay together ... how he would feel being with me and my epilepsy and having a child. I wonder if he would be happy or if he would worry all time, would he still want a child with me?

All I told him was I'm scared to have kids but not why. I'm scared to have kids because of my seizures and my medicine, I don't want to harm my child. ”

“ Now that I'm in my 30s, I do want kids. I think it might be at the upper end of not being able to have them now ... every single medication for my inflammatory disease that I've been on and pumped my body full of, I'm unsure that I could ever actually have a healthy baby. ”



UCB's Commitment to Patients



Pregnant and Lactating Women Living with a Serious and Chronic Illness Experience Unique Challenges

CHALLENGE 1

Limited information on the **impact of uncontrolled disease** on pregnancy outcomes

CHALLENGE 2

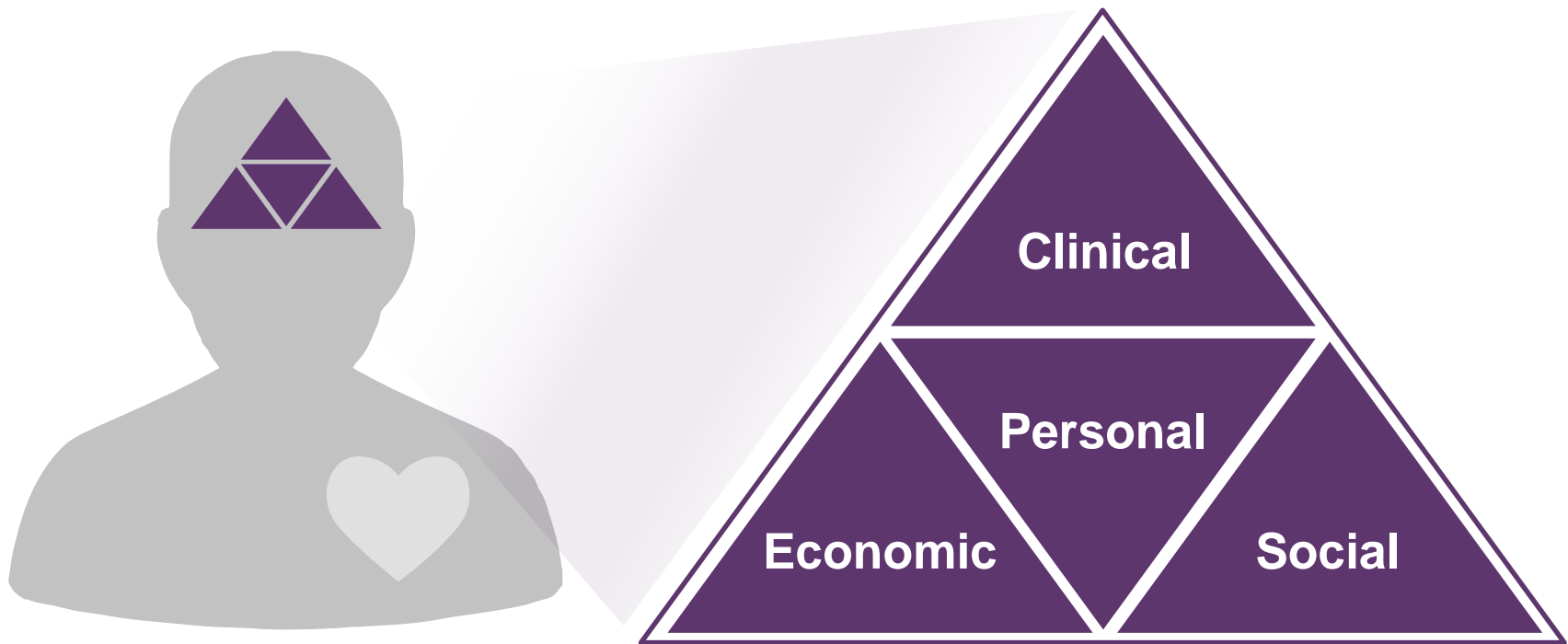
Limited information to **inform benefits and risks of medications** used during pregnancy and lactation

CHALLENGE 3

Poor and inconsistent communication of **benefit-risk of medicines** used by these women



UCB Engages with Patients to Understand their Needs



For women living with immunological conditions, the prospect of planning to have children or expanding their families **raises questions** about their health and medicines used for their care.

Women of Child-bearing Age Living with Autoimmune Conditions Have Unique Needs

NEED 1

If and how their disease may affect **their ability to have children** (including fertility)

NEED 2

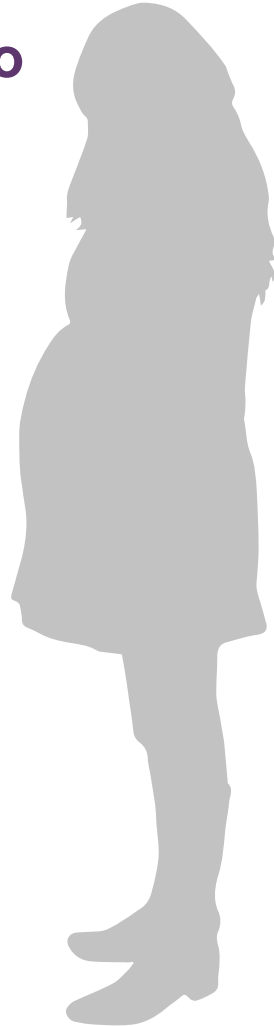
How **pregnancy may affect their disease** and how their condition may affect their pregnancy

NEED 3

Whether **medicines taken** for their disease before, during, or after pregnancy might affect their baby

NEED 4

Breastfeeding has **multiple benefits for both mother and child**, and with advancements in science and knowledge, choosing to breastfeed should not be a trade-off choice between the health of the mother and that of the baby



Programs to Advance Research and Outcomes Specific to Pregnant and Lactating Women



UCB's Commitment to Patients

We are committed to contribute to research and education in the **management of women of child bearing age** with rheumatic diseases and Crohn's disease through our research initiatives

UCB research

Two comprehensive studies to obtain more robust data on the potential transfer of certolizumab pegol (CIMZIA[®]) during pregnancy and lactation.

American Gastroenterological Association-UCB Partnership



Challenge: Currently, there is lack of accessible and accurate information available to WoCBA with inflammatory bowel disease (IBD) about the risks of and opportunities for starting a family

UCB Approach: Collaborate and co-create a multi-year partnership with the leading professional organization in gastroenterology, The American Gastroenterological Association (AGA), to create accessible and accurate information for WoCBA with IBD and foster discussion

Output: Through the partnership, AGA and UCB are focused on:

Research - Create a base of knowledge on issues that face women of childbearing age and health-care providers, ensure campaign materials resonate with patients and HCPs (GIs and OBs), and measure the impact of our educational interventions on patients that leads to a clinical pathway

Coalition and Consensus Building - Organize an in-person meeting of experts to finalize recommendations for inclusion in a series of clinical tools to improve care for women with IBD

Provider/Patient Outreach - Create an educational/outreach campaign targeted at women and partners of childbearing age and the physicians who care for them

Strategic
Partnerships

Evidence
Generation

Advocacy
Activities

ConcePTION Tackles the Issues Facing Pregnant and Lactating Women



Innovative Medicines Initiative: World's biggest public-private partnership (PPP) in the life sciences, between the European Union and the European pharmaceutical industry.

ConcePTION: Develop new methods used to close information gaps on effects of medications used during pregnancy and lactation; 12 pharmaceutical and 2 EFPIA partner in research companies; public consortium selection Q1 2018; project work begins Q1 2019.

Patients

Physicians

- **Alternative data generation** for pregnancy outcomes, including long-term outcomes
- **Harmonize data elements** for pharmacovigilance
- Develop and validate a **lactation model** in a species that more closely parallels human lactation physiology
- Establish a **Europe-wide breast milk biobank and analytical center** for drug analysis
- **Education and outreach**

Small Industry Recommendations



Small Industry Recommendations

- ❑ **Need to enhance disease specific research and better understand impact of chronic diseases on pregnancy and lactation**
 - ❑ Developing a harmonized approach for women of childbearing age in terms of collecting, interpreting, and analyzing data more effectively for this sub-population.
 - ❑ Agreed upon by all stakeholders such as federal agencies, medical societies, industry, and patient association
 - ❑ From real world evidence, registries, academic databases
- ❑ **Need to enhance drug specific research in women of childbearing age focusing on pregnancy and lactation**
 - ❑ Assessing the need for PK studies to ensure that women who need to be treated during pregnancy are getting benefit from their medicines.
 - ❑ Establishing partnership with biobank repository for researching drug levels in breastmilk
 - ❑ Better understand the ethical requirements for conducting clinical research in pregnant and lactating women
 - ❑ Design patient preferred studies to ensure a more informed benefit:risk evaluation by the patients considering family planning
- ❑ **Need harmonized approach for communication to patients and their providers to enable informed decision making and benefit:risk assessment.**

Partnering to Empower the Patient For Comprehensive and Coordinated Care

