Should we fast-track the approval process for pregnant women?[1]

UCB had developed a new drug for an autoimmune disease that primarily affected women. The drug was in the early stages of clinical trials. Unlike existing treatments on the market, it promised to be safe for pregnant women and their unborn babies. However, only a study on actual pregnant women could confirm this. Should UCB include pregnant women in the clinical trials? Or should it wait until the treatment was approved before collecting evidence for pregnant women?

UCB

Founded in Belgium in 1928 as Union Chimique Belge, UCB had morphed through successive acquisitions and divestments into a multinational biopharmaceutical company, specialized in neurology and immunology. In 2024, the company operated in 36 countries, with a workforce of around 9,000 people. Its drugs and solutions reached an estimated 3.2 million patients worldwide.[2]

In 2015, the changing environment, characterized by healthcare budgets under pressure and more engaged patients, inspired UCB to launch its *Patient Value Strategy*, putting patients at the center of its purpose. In parallel, the company embarked on its sustainability journey, starting with an assessment of where the company stood, and progressively and steadily aligning its governance and culture to its new purpose to "create value for patients now and into the future" (**Exhibit** 1).

Patient centricity

Putting patients at the center of UCB's purpose meant recognizing individual patients' needs, specific circumstances and treatment schemes. This implied, for example, focusing research and innovation efforts on unmet medical needs, and ensuring access to existing drugs through engagement with national health systems or alternative programs and initiatives, where relevant. It also implied engaging with patients, not only as end-users, but as key voices during all stages of the development and commercialization process.[3]

One illustration of UCB's patient-centric approach was the Women of Childbearing Age (WoCBA) Program. The program sought to advance knowledge about treatment efficacy and risks for pregnant women living with chronic diseases. Pregnant and breastfeeding women had been systematically excluded from pharmaceutical clinical trials for fear that the tested treatment would cause malformations or other harm to the foetus or baby. As a result, very few treatments were evaluated adequately for use during pregnancy and breastfeeding. Most did not provide information on use when pregnant or breastfeeding. Yet, an estimated 90% of women took medication at some stage during their pregnancy or when breastfeeding.[4] Some chose to discontinue treatment for fear of

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[1] Date: May 2025. This case was prepared by Prof. Estelle Cantillon as a basis for discussion at the fourth UCB-SBSEM "Business and Society" symposium in May 2025 to illustrate the use of decision frameworks in the context of difficult decisions. The case is based on actual events, but some names, dates, and numbers have been altered to protect the protagonists' privacy or commercially sensitive information.

[2] UCB Integrated Annual Report 2023.

[3] https://www.ucb.com/about-ucb/sustainability/patient-engagement (accessed April 11, 2025).

[4] Source: https://www.imi-conception.eu/ (accessed 10 April 2025).

harmful consequences for their foetus or babies, with potentially serious implications for their own health.

The Women of Childbearing Age Program collaborated with other industry and healthcare stakeholders to address this data gap through research. It supported the creation of data registries where physicians could report observed adverse events in their patients. UCB also contributed to industry-wide efforts to develop guidelines for the safe inclusion of pregnant and breastfeeding women in clinical trials.[5] Awareness among regulators was increasing. The European Medicines Agency and the US Federal Drug Administration had opened the door to including pregnant and lactating women in clinical trials.[6]

Ethical Decision Making at UCB

Dilemmas are unavoidable in business and UCB was no exception. To promote its employees' awareness about the impact of their decisions on UCB stakeholders and help them navigate difficult decisions, UCB had developed the Ethical Decision-Making tool (**Exhibit 2**). The tool defined ethical dilemmas as decisions that involved a breach of core human values (such as respect, integrity, or transparency), generated unequal impact on stakeholders, and/or had no obvious solution that was best for all.

Once an ethical dilemma was identified, the tool provided a method to explore it from different stakeholder perspectives and engage in conversation to resolve it. This was done in groups of 10 to 15 people, designed to encompass a diversity of views. For example, an employee with direct experience with the condition could be involved in a discussion about drugs for that condition. External stakeholders, such as physicians, patients, scientists or regulators, could be invited. Each participant was assigned a perspective (individual, community/society/planet, patients, or UCB) and asked to reflect on a number of questions from that perspective (**Exhibit 3**). Participants were explicitly encouraged to consider implications not only in the present but also in the future.

The tool was supported by the Ethics and Business Integrity team at UCB which offered training on how to use it and coaches to moderate the discussion if needed. It was also embedded in the company's code of conduct and part of induction training for all new staff. As of 2024, the tool was increasingly used at different levels of the organization, including the executive committee.

A promising new treatment

UCB had developed a promising new drug for a chronic autoimmune condition that mainly affected women during their childbearing years. The condition, if untreated during pregnancy, was associated with an increased risk for adverse pregnancy outcomes (such as miscarriages, premature delivery, pre-eclampsia) and hence significant risks for the mother and the unborn baby. Existing treatments entailed risks too, as they crossed the placenta and therefore reached the foetus.[7] Based on the properties of the new molecule and results from the pre-clinical trials, the scientists working on the drug had the conviction that this would not be the case for the new treatment, making it safe for the unborn baby.

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[5] Source: https://www.ucb.com/solutions/healthcare-professionals/women-of-childbearing-age and https://www.ucb.com/solutions/magazine/detail/article/closing-the-knowledge-gap-including-pregnant-and-breastfeeding-individuals-in-clinical-trials (accessed 10 April 2025).

[6] https://www.fda.gov/drugs/development-resources/division-pediatrics-and-maternal-health-clinical-trials-pregnant-women (accessed 11 April 2025).

[7] In fact, many effective treatments were contraindicated or not recommended during pregnancy.

New drugs went through a long approval process. Once a drug had been developed, it first underwent pre-clinical trials, including in-vitro, ex-vivo and animal testing to evaluate its risks. Only then was the new drug tested on humans. Clinical research typically consisted of three phases that evaluated the safety, appropriate dosage, efficacy and side effects of the drug (**Exhibit 4**).

In 2024, the results of the standard reprotoxicity pre-clinical studies on non-human primates established the lack of transfer of the new drug through the placenta during pregnancy. The first phase 3 study had been completed, with promising results on efficacy and safety. A second study was being launched. If all continued to go well and the new drug was approved, one could expect its commercialization in 2029.

Should we include pregnant women in the phase 3 trials?

This is when Marie Teil, Head of the Women of Childbearing Age Program intervened. Could we implement a study that would specifically look at pregnant women and the transfer of the drug to the baby in parallel with the phase 3 trials?[8]

The potential upside of this decision was clear. Confirming in pregnant women patients that the drug did not cross the placenta would prove that it was safe for pregnant women, a major breakthrough for women around the world suffering from this autoimmune condition. Doing so before approval would ensure this information would appear explicitly in the drug notice, providing reassurance to physicians and patients.

But the risks were equally clear. First, testing a drug on pregnant women would break with the current industry and societal norm of excluding pregnant women to avoid any risk for the foetus. This risk could be mitigated by limiting the number of women in the study and administering the drug only after the first trimester of pregnancy was completed, thereby avoiding the most critical time for developing malformations in the foetus. Still, it was not nil. Second, the study would need to last until after delivery. This would delay the clinical trials by a few months, but more importantly, accidents independent of the drug (e.g. a miscarriage for another reason) could not be ruled out. Yet, it would be impossible, given the small sample size, to establish that these accidents were not due to the drug. Because these data would be part of the approval application package, this could jeopardize the approval.

The alternative was to wait for the drug approval and then collect data and run studies on pregnant women. This would delay certainty about product safety for physicians and their pregnant women patients by 2 to 3 years.

The issue was brought forward to UCB's Benefit Risk Board (BRB). The BRB was a company-wide committee that monitored and advised on product-specific benefit-risks. The Board routinely engaged with patients and doctors, alongside inputs from inside the organisation (data from studies, expertise). In this case, the Board asked the Ethics and Business Integrity team to run the Ethical Decision-Making tool for this decision. Their inputs would be included, alongside the available data from the first study, patient and doctor testimonies, and expert advice by Marie Teil to reach a decision. The decision would then be sent to the executive committee for final approval.

[8] In technical terms, studies that look at the way the body interacts with a drug during the duration of exposure are called pharmacokinetic (PK) studies.

Exhibits

Exhibit 1: UCB's purpose

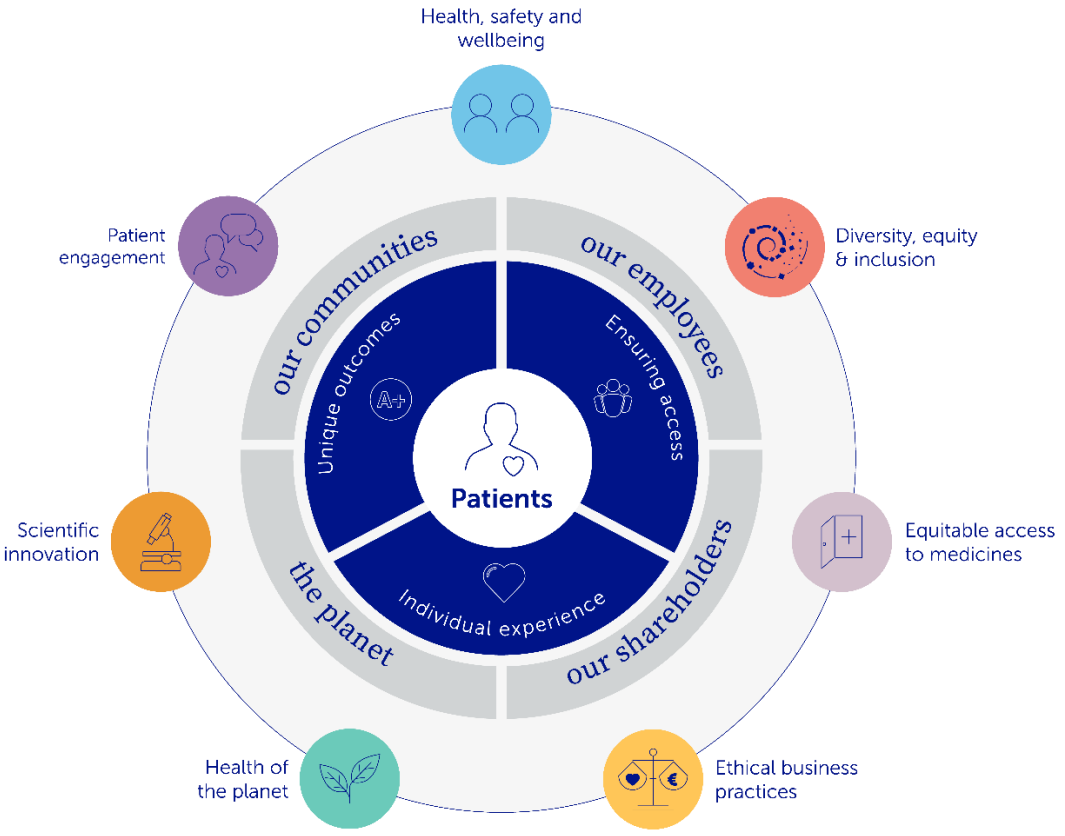


Exhibit 2: The Ethical Decision-Making tool.

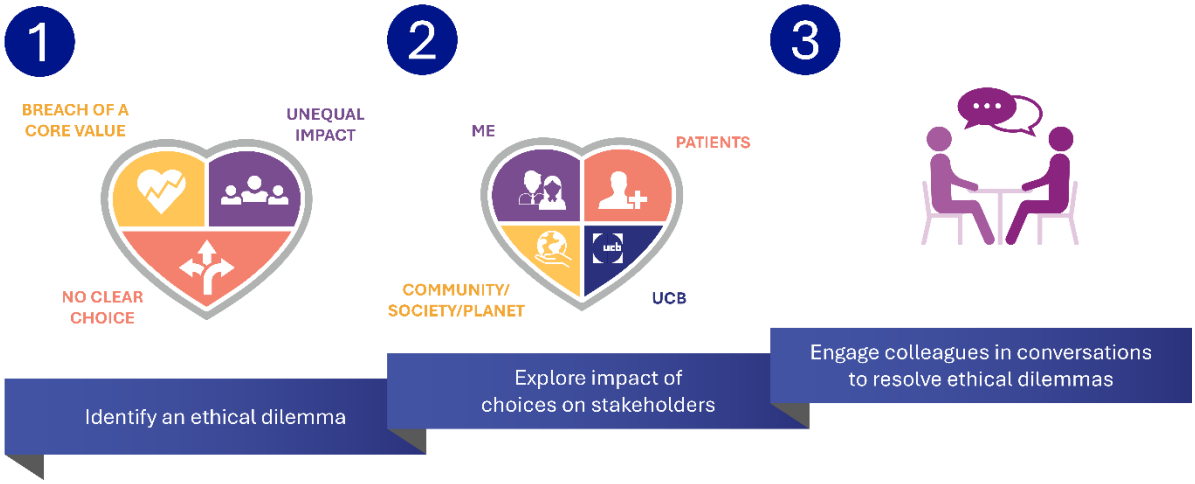
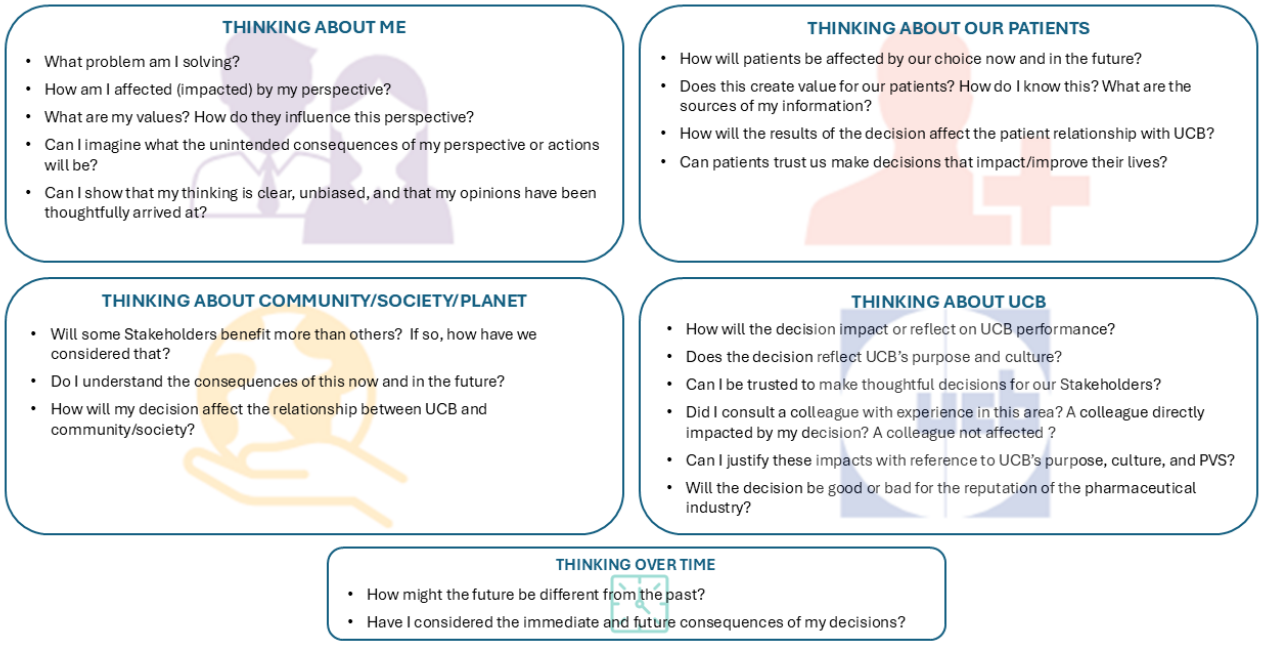
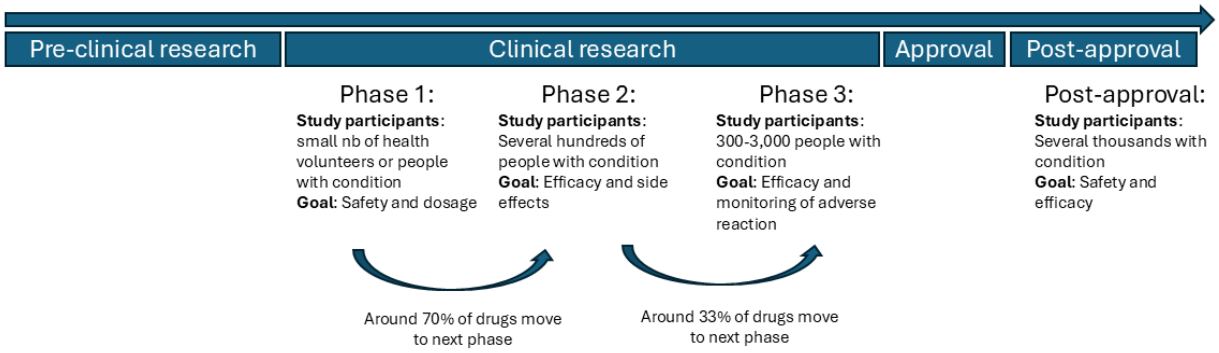


Exhibit 3: Stakeholder perspective questions in UCB's Ethical Decision-Making



Source: Company material. PVS stands for Patient Value Strategy.

Exhibit 4: Stylized representation of the drug approval process



Source: Adapted and illustrated by the author based on https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process (accessed April 11, 2025).