Patient Safety: Pre-market

At Janssen, patient safety is always a priority. Below are key questions and answers about the process for monitoring patient safety *before a drug is approved* by health authorities.

*The following details safety monitoring in the U.S., where the health authority is the Food and Drug Administration (FDA).

What happens during the drug development process?

Drugs that are prescribed by licensed healthcare providers have been studied in **clinical trials**—an important process to evaluate and understand benefits and risks to patients.

After we have determined a study drug is ready to study in humans, **clinical trials are conducted in three key phases**. Each of these three phases is an important step toward understanding how the drug may be both effective and safe for patients. The process of bringing a drug to market may take more than 10 years.

PHASE I	A study drug is given to a small number of participants to **EVALUATE SAFETY** of the medicine. This is often done in healthy volunteers (people without any known disease or conditions).
PHASE II	**DETERMINE EFFECTS** of the study drug on disease or condition being evaluated, and determine what doses seem to be effective and safe for testing in a larger group of patients.
PHASE III	**COMPARE STUDY DRUG** with a sugar pill (placebo) or "standard" drug. These studies are generally much larger and longer in duration than Phase I and II studies.
FDA	At the completion of Phase III, we **SUBMIT APPLICATION for approval to the FDA.**

How does Janssen help to ensure patient safety during clinical trials?

- **REVIEW side effects** reported by physicians or Health Care Providers (HCPs), also called adverse events
- **COLLECT & REVIEW adverse events** and take all adverse events seriously
- **SHARE clinical trial safety data** with the FDA, following FDA regulations

What does Janssen do with the information once the clinical trials are completed?

- Submit collected information to the FDA for review
- If the drug is approved by the FDA, Janssen and the FDA then create a drug label to educate prescribers and patients about safe use as well as common side effects
- Drug is then available for prescribing to patients

If I have more questions about Janssen's approach to safety, where can I learn more?
For additional information please visit: **https://janssen.com/patient-safety-information**

www.fda.gov
Individuals depicted are models, for illustrative purposes only.

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Patient Safety: Post-market

At Janssen, patient safety is always a priority. Below are key questions and answers about the process for monitoring patient safety after a study drug is approved by Health Authorities **and is available for prescription by health care providers.**

*The following details safety monitoring in the U.S., where the health authority is the Food and Drug Administration (FDA).

After a drug is available to patients by prescription, does Janssen continue to monitor safety?

Yes. On a continuous basis Janssen's dedicated healthcare professionals:

- **COLLECT** information received from patients and health care providers
- **ANALYZE** known events and those not seen in the clinical trials
- **REVIEW** the literature for publications of adverse events
- **EVALUATE** to assess trends as needed
- **COLLABORATE** with internal and external experts, and
- **SHARE** collected information with the FDA

Janssen follows all FDA regulations for providing post-market safety data.

What happens if Janssen identifies a problem while the drug is available?

Depending on the nature of the problem, Janssen and/or the FDA may:

- **UPDATE** a drug label and/or patient information to ensure awareness of a potential safety issue or safe use of the product
- **SEND** a letter to communicate important safety information to physicians and health care providers
- **REMOVE** a drug from the market either temporarily or permanently

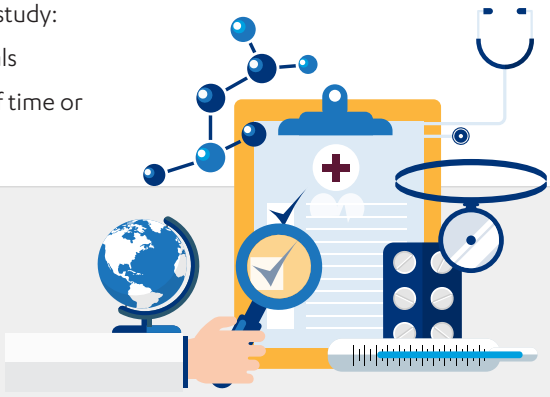
Are there more studies after a drug is available for prescription?

For some drugs, clinical trials continue in the post-marketing setting. These trials are called phase IV studies.

PHASE IV

Janssen may decide to voluntarily conduct a phase IV study, or it may be required by the FDA. These phase IV clinical trials may study:

- Side effects that may not have been seen in earlier trials
- How well a new treatment works over a long period of time or when used widely



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