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Toxicology in R&D

Toxicology, or the "science of safety," aims to understand the potential effects that various materials can have on individuals.[1] In the research and development (R&D) of new therapeutics, toxicology plays a crucial role from start to finish, helping to ensure safe treatments are provided to patients.

What can be "toxic?"

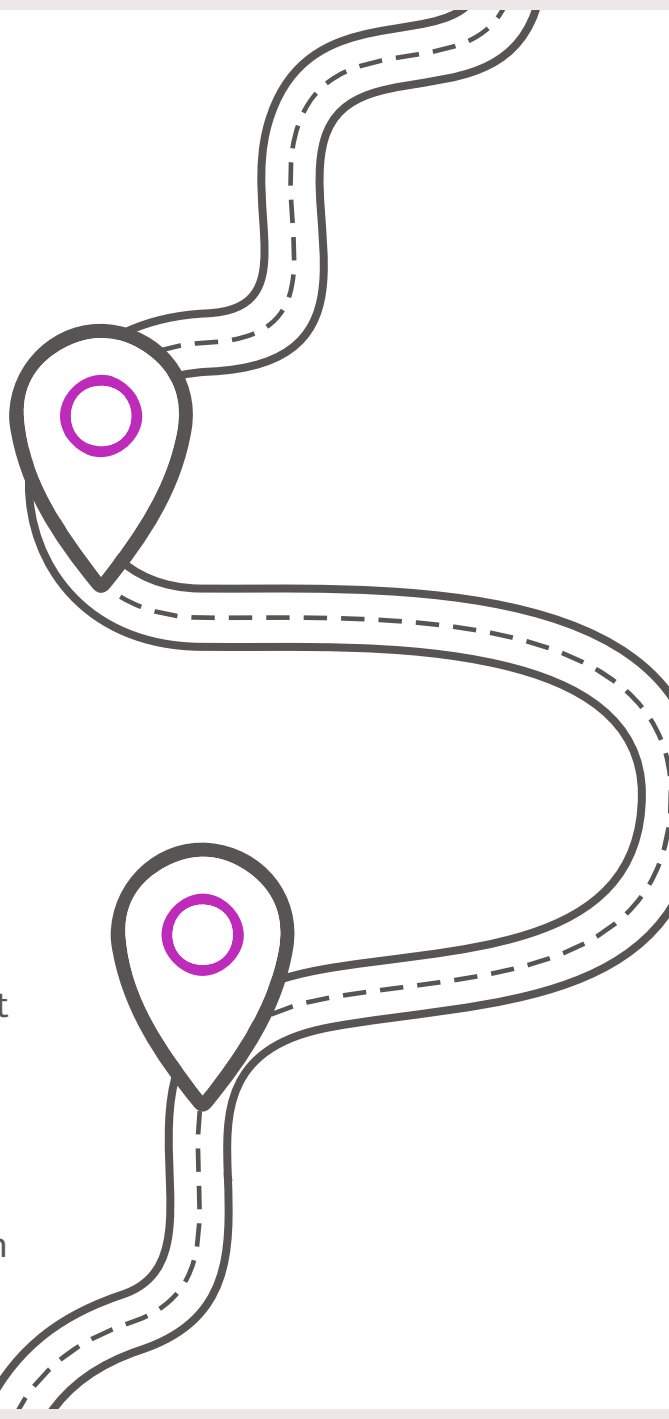
The answer is more complex than you may think. Everything can be "toxic," depending on the dose, or amount. Take water, for example. When consumed at extremely high amounts, water intoxication can be fatal.[2]

So, who is responsible for making sure we understand the safety profile of the things we put into our bodies to treat diseases?

Toxicologists

Toxicologists specialize in understanding the effects that chemicals might have on the human body. **In R&D, they play a key role in all aspects of drug discovery.**

Where does a toxicologist's role begin in drug discovery? At the very beginning.



Target Identification

Developing a therapeutic often begins with target identification, which is the identification of a process within the body that plays a role in disease.

- Toxicologists look at the target and its relation to:
  - The disease
  - Healthy cells and tissue
- Understanding the target's role beyond the disease helps uncover any potential adverse events that may occur when it is influenced.

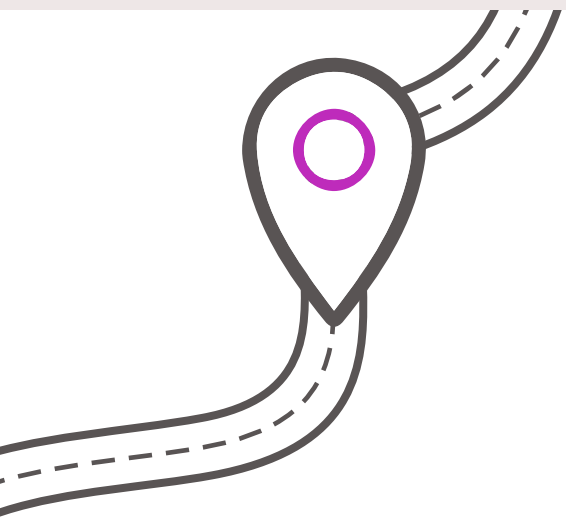
Drug Identification and Testing

Targets can be modulated, or influenced, by a chemical or protein (like an antibody).

- When modulation affects a disease process, the result is a drug.
- Scientists identify potential new drugs, and then turn to toxicologists to understand the safety profile.

The type of drug (e.g., small molecule, biologic, etc.) gives toxicologists an idea of the safety profile, but each drug must be carefully studied to understand potential adverse events.

Toxicologists try to understand the adverse effect profiles of molecules being developed very early, to help inform future development of the therapy, as well as to serve as key learnings for further research.

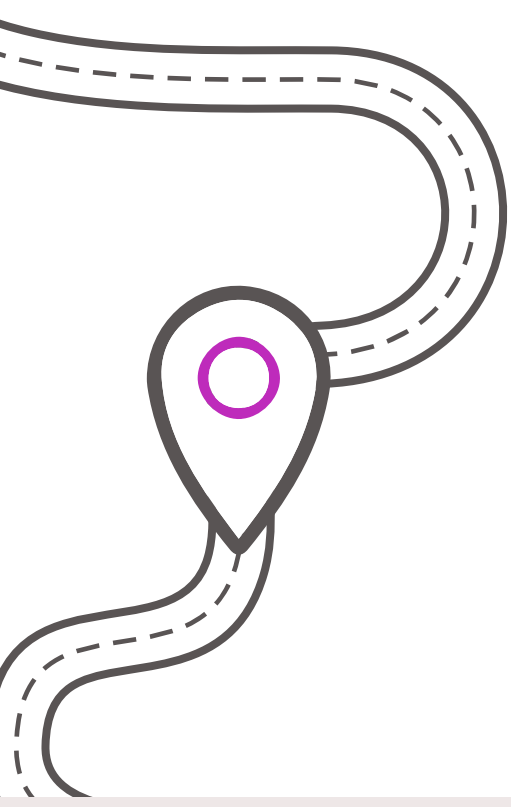


Clinical Trials

Toxicologists play a critical role in determining which therapies move on to clinical trials and which don't. And crucial to that decision is the risk/benefit profile.

Factors considered in this assessment include:

- Dose
  - Does the dose produce a therapeutic effect without intolerable adverse effects?
- Severity
  - Are the adverse effects bothersome or harmful?
- Management
  - Can the adverse effects be understood physiologically, allowing the toxicologists to help inform the clinical team of opportunities to manage them?
- Condition
  - Is the condition being treated severe enough that patients and physicians may tolerate a higher risk profile (e.g., late stage cancer)?



Drug Availability

Once a drug has been through the rigors of development, testing and clinical trials, it can then be used for its original purpose: **to benefit patients.**

Through the work of toxicologists, physicians have a deep understanding of the adverse effect profiles of the drugs they prescribe and are equipped to watch for and/or manage any issues that may arise over the course of treatment.

Ultimately, the culmination of a toxicologist's work is ensuring safe treatments are provided to patients.

1. Toxicology. National Institute of Environmental Health Sciences. https://www.niehs.nih.gov/health/topics/science/toxicology/index.cfm. Accessed 11 November 2020.
2. Farrell DJ and Bower L. Fatal water intoxication. J Clin Pathol. 2003;56(10):803–804.