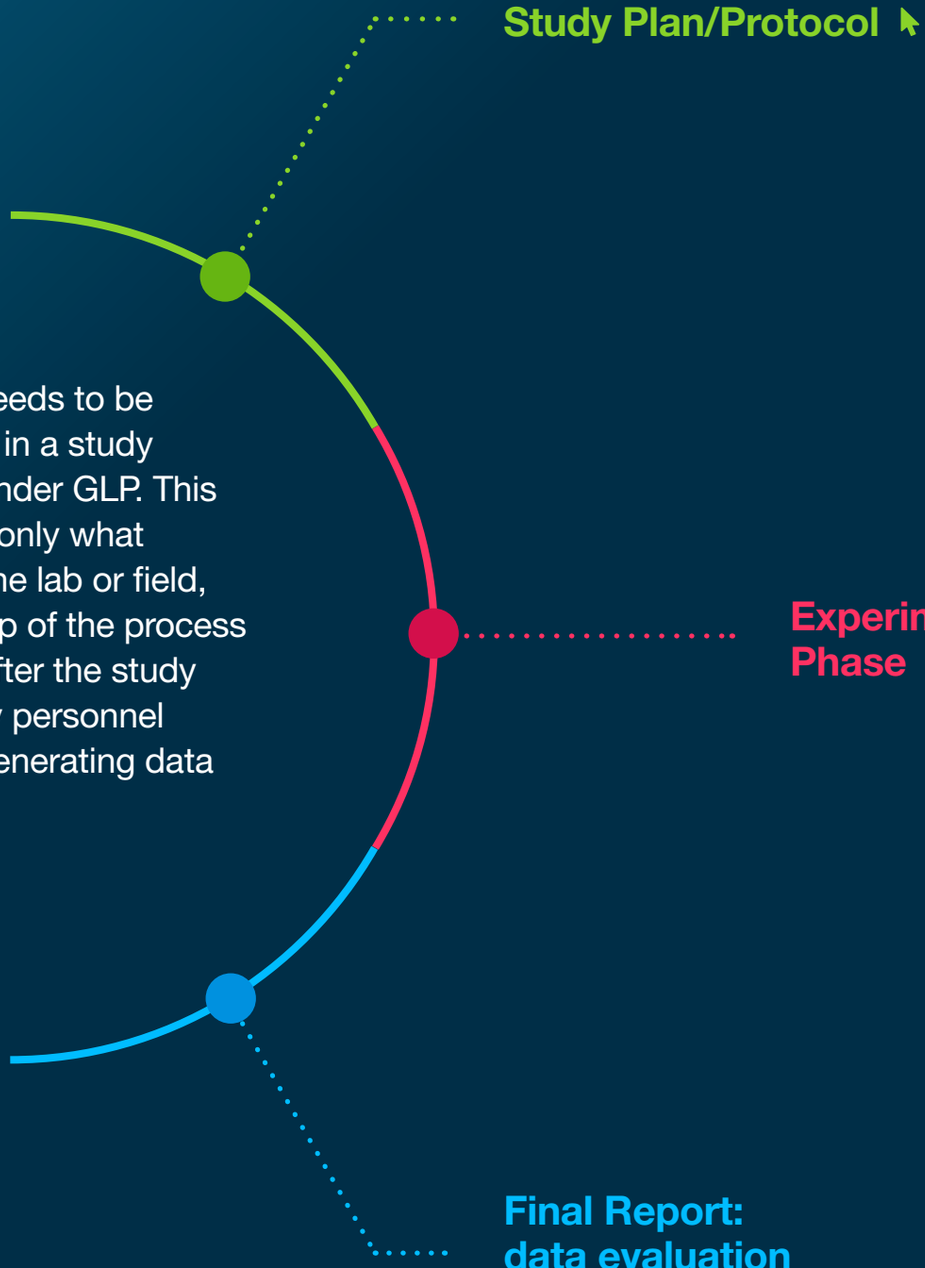
How is a GLP study conducted?



Everything needs to be documented in a study conducted under GLP. This includes not only what happens in the lab or field, but every step of the process before and after the study including any personnel involved in generating data for the study.

Hover over the different elements to learn more.

What happens if the conditions of a GLP study change?

Whenever the conditions of a study change, the changes need to be recorded and evaluated. The types of changes that could affect the Study Plan/Protocol are:

Study Amendment:

an intended or planned change to the Study Plan/ Protocol after the study initiation date.

Study Deviation:

an unintended, unforeseen, or unplanned change to the Study Plan/Protocol after the study initiation date.

GLP studies are very complex, time consuming and expensive due to the time needed for testing to assess the product safety and effectiveness while adhering to the quality standards required by regulatory agencies.

For example, with crop protection products, only 1 out of 160,000 compounds meets the required criteria and reaches the market. The time to demonstrate that a product is safe, effective and of a good quality typically takes between 8-12 years and includes hundreds of studies.