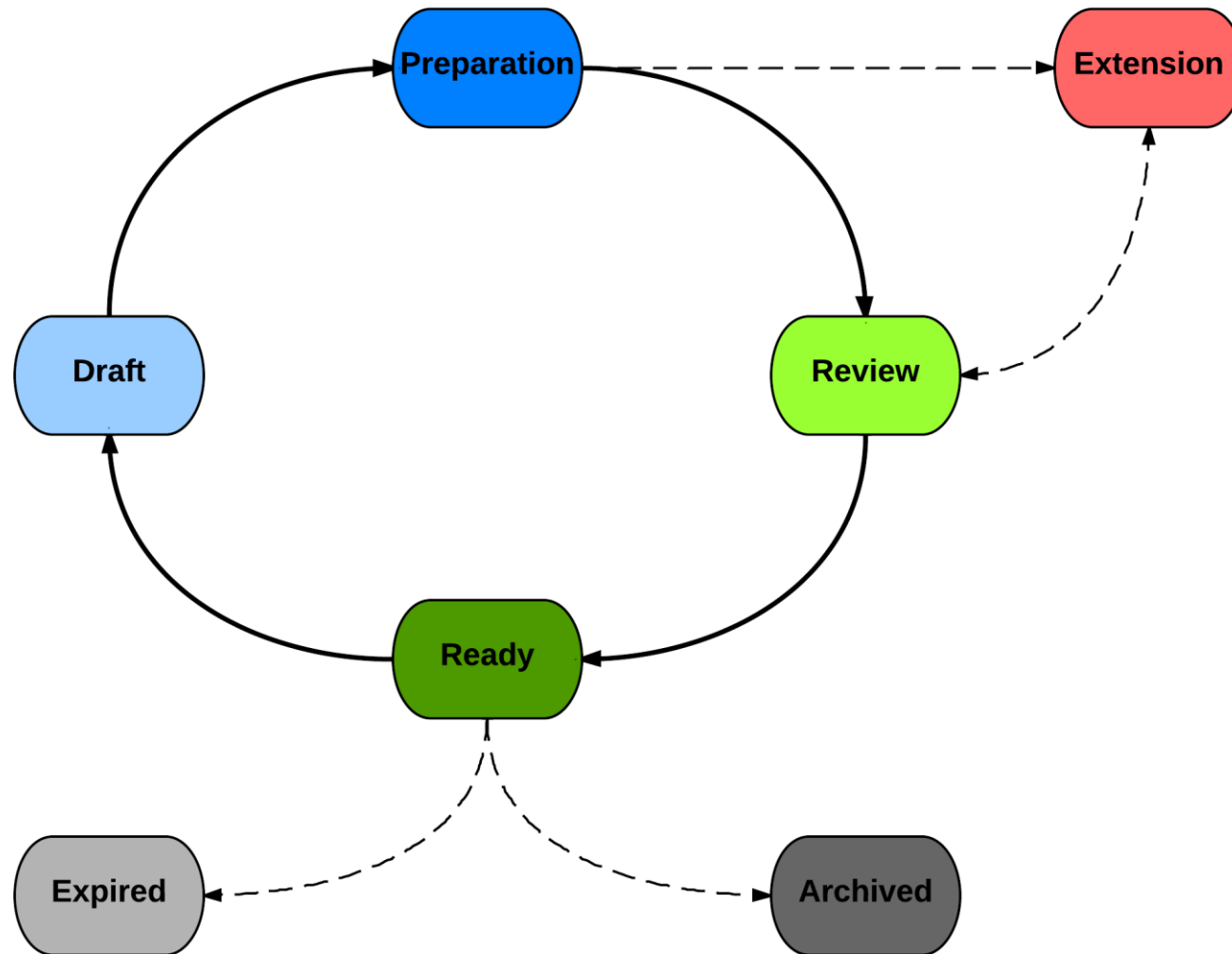


PRISM Life Cycle



Draft

The **Draft** state is the first phase of a study. When a study is first loaded in **InspectionReady**, and every time a study advances to a new version, it enters the **Draft** state. The **Draft** state is a period of setup where the following **Study Leader** actions can take place:

- ✓ **Accountable Roles** assigned
- ✓ **Response Owner** roles assigned
- ✓ **Study Tasks** created and edited
- ✓ **Project Administrators** added and removed
- ✓ **Study Leader Messages** turned on and off

While a study is in the **Draft** state, **Response Owners** do not have access to work on any tasks. Additionally, the **Study Leader** cannot publish (advance to the **Preparation** state) the study until all of the **Response Owner Roles** have been assigned.

Once the **Study Leader** has completed all of the study setup requirements, the study can be advanced from the **Draft** state to the **Preparation** state. If the **Study Leader** has activated study messages prior to publishing the study, **Response Owners** will receive email notification that their **Response Owner Tasks** are available to be completed.

The amount of time that **Response Owners** have to complete **Response Owner Tasks** will depend on the **Time to Complete** date selected by the **Study Leader** when the study was published to the **Preparation** state.

Preparation

When a study is advanced to the **Preparation** state, **Response Owners** will receive email notification that their **Response Owner Tasks** are available to be completed. **Response Owners Tasks** will automatically populate on each **Response Owner Calendar** and **Response** tab.

During the **Preparation** state, **Study Leaders** and **Response Owners** can engage in the following study related activities:

- ✓ Create and resolve **Issues**
- ✓ Create and resolve **Action Items**
- ✓ Create and resolve **Study Tasks** (also known as **Response Tasks**, but not to be confused with **Response Owner Tasks**)
- ✓ Update **Compliance Notes** for study questions
- ✓ Complete **Response Owner Tasks**
- ✓ Indicate **CRO Oversight** for study questions
- ✓ Indicate **Inspection Vulnerabilities** for study questions

The duration of a study **Preparation** state is three months. If more time is needed to complete study related tasks beyond this three month period, the **Study Leader** can advance the study to the **Extension** state.

Extension

The **Extension** state is designed to provide **Study Leaders** and **Response Owners** with more time to complete study related activities if the three month period provided during the **Preparation** state proved insufficient. The same study related activities that were eligible to be completed during the **Preparation** state can also be completed during the **Extension** state.

A study can also be returned to the **Extension** state from the **Review** state if a **Study Leader** determines that there are aspects of the study that require additional review before the study can be advanced to the **Ready** state.

Review

The **Study Leader** can advance the study to the **Review** window from either the **Preparation** or **Extension** states. Once the **Review** window has been initiated, **Response Owners** no longer have the opportunity to interact with **Response Owner Tasks**. However, **Response Owners** can still complete **Action Items** and resolve study **Issues** during the **Review** window.

The **Review** window is meant to provide **Study Leaders** with the opportunity to inspect completed **Response Owner Tasks** and other study related items. Once a **Study Leader** feels that all aspects of a study are compliant with regulatory and organizational guidelines, the study can be advanced to the **Ready** state. However, if the **Study Leader** feels that there is any aspect of the study that requires further inspection preparation, they can return the study back to the **Extension** state.

Ready

A **Study Leader** can advance a study to the **Ready** state once they feel confident that all aspects of the study are compliant with regulatory and organizational guidelines. The end date of the **Ready** state is automatically set to one year from when the **Study Leader** initiated the **Preparation** state. Once a study enters the **Ready** state, **Response Owners** are unable to make any adjustments to **Response Owner Tasks**.

Expired

When a study is advanced from the **Ready** state to the **Draft** state, the **PRISM** life cycle starts over with a new version. At that point, the prior version of the study is set the **Expired** state and can be accessed by **Study Leaders** and **Response Owners** for future reference. The following occurs when a study is advanced from the **Ready** state to the **Draft** state of the next study version:

- ✓ Open **Issues** and **Action Items** remain open and carry forward from the prior version, to the new version of the study
- ✓ **Study tasks** (also known as **Response Tasks**, but not to be confused with **Response Owner Tasks**) are archived
- ✓ **Response Owner Tasks** are set to incomplete

Archived

Once a study is completed, the **Study Leader** sets the study to the **Archived** state. This will render the study as inactive within **InspectionReady** and cease to generate any additional versions of the study. However, all historical versions of the **Archived** study can be accessed by **GIG Users**, **Study Leaders**, and **Response Owners** for future reference.