U.S. FOOD & DRUG ADMINISTRATION

Guidance Snapshot

Translation of Good Laboratory Practices Study Reports: Questions and Answers

Draft Guidance for Industry

What is Covered in This Guidance?

This question-and-answer document is intended to clarify FDA's recommendations concerning the translation of study reports from a non-English language into English for studies conducted in compliance with good laboratory practice (GLP) regulations (21 CFR part 58). GLP studies include, but are not limited to nonclinical toxicology studies, safety pharmacology studies, and device safety studies received by different FDA Centers.

Why is This Guidance Important?

A large number of nonclinical toxicology studies are conducted by testing facilities located outside of the United States. In instances where the GLP study report is generated in a language other than English, the study report is translated into English for FDA submission. This guidance provides FDA's expectations and requirements that the translated study report be an accurate, truthful, and complete representation of the original report. This is important to ensure reliable study data are submitted to FDA for review.

Do the Guidance Recommendations Apply to the Translation of Other Study Reports Submitted to FDA?

This draft guidance does not address the translation of other study reports. FDA may issue guidance regarding questions & answers for the translation of other study reports submitted to FDA in support of marketing authorizations as appropriate..

Guidance Snapshots are a communication tool and are not a substitute for the guidance document. To learn more about the translation of nonclinical toxicology study reports, read the guidance.

What Translation Details are Discussed in This Guidance?

Translator Qualification

English translation should be performed by a translator with education, training, experience, or combination thereof, in English and in the native language. The translator should be familiar with translating medical and scientific documents into English.

Translation Statement

The translator should generate a signed and dated translation statement, separate from the translated nonclinical study report, stating the translated document is a truthful, accurate and complete representation of the original GLP study report. The statement should be placed immediately in front of the translated study report cover page.

Translation SOP

Procedures for GLP study report translation should be established. The procedures should include translator qualifications and requirements for the translation, such as documentation, and completeness checks.

Translation of Amended Study Report

Each amendment to the original GLP final study report should be translated as a separate document. The final study report and any report amendments should be kept as separate documents.

Translation of Tables

The entire GLP study report, including all of the tables, appendixes, and contributing scientist reports, should be accurately and completely translated into English in the translated study report. Data tables should include the same tabular data, with the same format and translated text.

Signatures in Translated Study Reports

The translated GLP study report should not be signed. The translated study report should include the typed name of the study director and the date the original final study report was signed. The translated study report should also include the names of contributing scientists, quality assurance auditor, and testing facility management.

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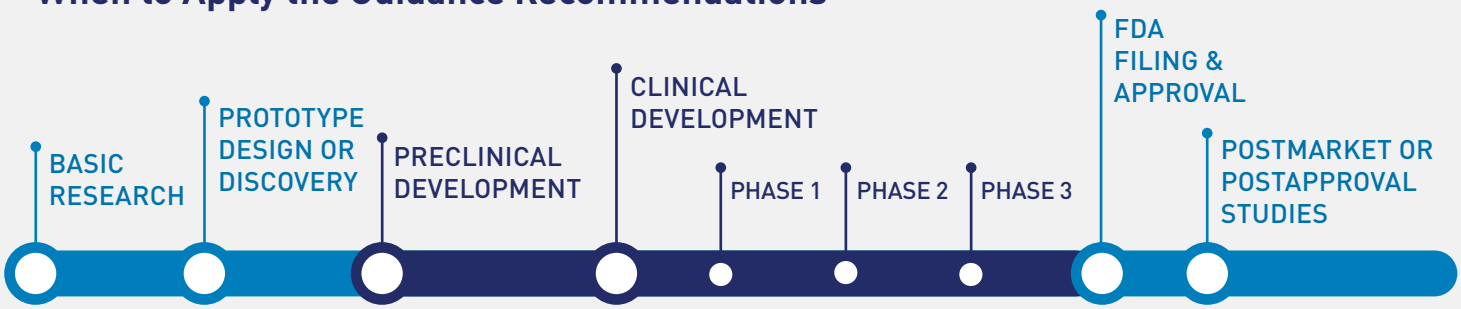
Completeness Check

This check should be performed by a second person on the final version of the translated GLP study report to verify the report format, tabular content, and figures (graphical representation of data) for completeness. All translations should be accurate, complete, truthful, and follow written processes and procedures to consistently ensure the quality of the study data.

Drug Development Timeline

When to Apply the Guidance Recommendations



During Preclinical and Clinical Development: This guidance provides the Agency's expectations to sponsors and nonclinical laboratories regarding the translation of study reports for studies conducted in compliance with GLP regulations.

Continue the Conversation

Share your thoughts on the draft guidance

Click here to provide official comments to the FDA Docket

Guidance Recap Podcast

Hear highlights from FDA staff

Speaker(s): Rick Wasko, Biologist in the Center for Drug Evaluation and Research's Office of Study Integrity and Surveillance

Click here to listen

Click here to read transcript

Guidance Snapshots are a communication tool and are not a substitute for the guidance document. To learn more about translation of nonclinical study reports, read the guidance. To see additional guidance Snapshots, **check out the pilot program**.