

EFS FAQs

Who should I contact if I am considering sponsoring an early feasibility study (EFS)?

An EFS Representative.

- Because the EFS Program is evolving and early feasibility study projects are managed differently than traditional feasibility and pivotal study projects, it may be beneficial to contact an EFS Rep before fully engaging the review team.
- The Rep can describe the current process and help prepare for your interactions with the subject matter expert reviewers.

When should I start the conversation with CDRH?

- You are encouraged to begin interacting with CDRH early in the device development process and to keep CDRH current on your progress.
- In turn, CDRH can keep you up to date on the evolution of the EFS Program.
- It is always important to contact CDRH prior to submitting an application to optimize communication, particularly for this developing program.

Why would I want to participate in the EFS Program?

The EFS Program provides a means for direct collaboration amongst the FDA, sponsors, and innovators. Potential benefits of the program include the following:

- Providing the earliest access to potentially beneficial medical devices to patients in the US.
- Review team familiarity with the technology throughout the product development process, applying a learn-as-you-go approach.

Potential benefits, cont.

- Use of a methodology for identifying appropriate information to justify study initiation from the beginning which can also be applied at each phase of clinical evaluation.
 - Ability to justify doing the right testing at the right time.
 - Documentation of the rationale for the information needed which may be useful if there are changes in the sponsor or review teams.
- Smoother transitions between phases of clinical evaluation.
- Capturing early feasibility data that is relevant to the US population and therefore directly supportive of subsequent US clinical studies.

How is an EFS different from a traditional feasibility/pilot study?

- An EFS generally involves a device or indication that is earlier in development as compared to those being evaluated in a traditional feasibility study.
- For an EFS, clinical data may be needed to advance the product development, with some nonclinical testing deferred until the device is more final or after the use is refined.
- An EFS may therefore be supported by less nonclinical data than would be expected for a traditional feasibility study.

How is the Pre-Submission process different for an EFS?

- The initial EFS Pre-Sub interactions will focus on the information needed to justify study initiation.
- Additional Pre-Subs and discussions may be needed to address other aspects of a future IDE submission, such as test protocols, the clinical study plan, and informed consent wording.
- In general, the EFS processes will be more interactive to facilitate the conduct of these studies in the US.

Why is conducting an EFS not an additional step or burden?

- The conduct of an EFS is optional.
- The perceived burden is the need to justify the information needed in the Report of Prior Investigations to support study initiation.
- Realizing that a lack of an adequate Report of Prior Investigations is a common reason for disapproval of an IDE, the EFS guidance describes a device evaluation strategy (DES) methodology to help communicate the rationale for the proposed information, which may include:
 - device design,
 - leveraged nonclinical,
 - supportive clinical information,
 - testing on the device to be used in the clinical study, with
 - consideration of the clinical study mitigation strategies that will be applied to reduce risks to study subjects.

Why is doing a DES not a burden?

- Although the application of this methodology is new for some sponsors, once mastered it can be readily applied to additional projects.
- This methodology can be used throughout product development to help reach agreement on the testing needed at each phase (e.g., traditional feasibility study, pivotal study, marketing application, post-approval) and to document the rationale behind the information to be provided.
- The use of the DES table is also optional; however, a rationale for the information to be provided in the Report of Prior Investigations is always needed.

Is an EFS always needed for an innovative device or new intended use?

No.

- Although an EFS may be an option, an EFS is not required. The type of study to conduct depends on:
 - whether the device design is still likely to change, is near-final, or final;
 - the amount of data available to justify study initiation; and
 - the purpose of the study.

EFS

- Device design may not be final, with changes anticipated
- Less nonclinical data available for the study device with potentially more reliance on device design and leveraged information
- Intended to provide initial insights

Traditional Feasibility

- Device design may be final or near-final
- Generally supported by more nonclinical or prior clinical data
- Intended to capture preliminary safety and effectiveness information and to adequately plan an appropriate pivotal study

Pivotal

- Final device design
- Clinical feasibility established and all IDE-level nonclinical data completed
- Intended to capture safety and effectiveness data to support a marketing application

Can I request to conduct an EFS if:

I HAVE A NEAR-FINAL OR FINAL DEVICE DESIGN OR AM USING A MARKETED DEVICE FOR A NEW INTENDED USE?

Yes.

- Although device changes may not be anticipated, the purpose of the study may fit within the definition of an EFS.

THE DEVICE IS MARKETED IN THE US BUT I AM MODIFYING THE DEVICE?

Yes.

- The amount of nonclinical data available to assess the modified device may be less than what would be expected to support a traditional feasibility or pivotal study and the purpose of the study may be to obtain initial insights.

Can I request to conduct an EFS if:

**THE DEVICE IS MARKETED
OUTSIDE OF THE US?**

Yes.

- An EFS may be considered, particularly if the device is being used for a new intended use or if nonclinical data are not available to support a traditional feasibility or pivotal study.

**THERE IS A CLINICAL STUDY OF
THE DEVICE HAPPENING
OUTSIDE OF THE US?**

Yes.

- An EFS may be considered, particularly if the device is being used for a new intended use or if nonclinical data are not available to support a traditional feasibility or pivotal study.

Can I request to conduct an EFS if:

THERE IS A GUIDANCE DOCUMENT OR RECOGNIZED STANDARD FOR THE TYPE OF DEVICE I AM USING?

Yes.

- An EFS may be proposed but depending on the novelty of the device design, it may or may not be acceptable to initiate the study without conducting the tests described in the guidance or standard.

I HAVE A CLASS II DEVICE AND WOULD USE THE 510(K) PROCESS TO SEEK MARKETING CLEARANCE?

Yes.

- The type of study you can request is independent of the type of future marketing submission and instead depends on:
 - whether the device design is still likely to change, is near-final, or final;
 - the amount of data available to justify study initiation; and
 - the purpose of the study.

Can I still do an EFS if I didn't identify my project as an EFS at the start of my interactions with CDRH?

Yes.

- However, it may be necessary to provide the rationale for the testing needed to justify study initiation and to reassess prior feedback provided by CDRH if a study is not identified as an EFS from the beginning.

Study Size Questions

IS THERE A LIMIT ON THE INITIAL NUMBER OF PATIENTS FOR AN EFS?

Not specifically.

- EFS are generally small studies (e.g., 15 subjects) which can be expanded if justified.

IF I REQUEST TO EXPAND MY EFS TO MORE THAN 15 STUDY SUBJECTS, WILL IT STILL BE CONSIDERED AN EFS?

Maybe.

- If the purpose of the study remains consistent with an EFS, or if device modifications are anticipated, the study designation may remain as EFS.
- If the device is final or near final and the purpose of evaluating the additional patients is more consistent with a traditional feasibility or pivotal study, it may be appropriate to transition into a different type of study.

Can I pool my EFS data with my pivotal study data in a marketing application?

Maybe.

- The purpose of an EFS is generally not to collect definitive safety and effectiveness data, but there are times when it may be acceptable to include the data captured under an EFS (e.g., for an HDE).
- EFS data can be submitted as *supportive information* in a marketing application when it is not appropriate to pool the EFS with the pivotal study data.

Can I transition directly from an EFS to a pivotal study?

Maybe.

- If clinical feasibility has been established, all IDE-level nonclinical data are completed, the device design is finalized, and the study is intended to capture safety and effectiveness data to support a marketing application, a pivotal study may be proposed.

Do I need separate IDEs for my EFS, traditional feasibility, and pivotal studies?

No.

- You can request to start a new phase of study under the same IDE number.

Is a device evaluation strategy table required in an EFS IDE?

No.

- A rationale for the information to be provided to justify study initiation is needed.
- Use of the tabular format for the device evaluation strategy is preferred, but not required.
- A sponsor, including sponsor-investigators, may work with the EFS Representatives and the review team to identify an alternative format for presenting their evaluation strategy.

Is the amount of nonclinical data needed in a Report of Prior Investigations for an EFS IDE the same as what would be needed for a pivotal study IDE?

Maybe.

- The amount of nonclinical data on the device to be used in the clinical study will depend on several factors, such as whether the nonclinical testing can be used to predict clinical performance and whether there is information that can be leveraged in place of conducting testing.

Nonclinical Testing Needs Examples

- If data are available from testing a prototype and the applicability of the data can be explained, the testing would not need to be repeated on the device to be used in the EFS clinical study.
 - Generally all testing would need to be completed on a device to be used in a pivotal study.
- If there are not tests that can predict the clinical performance of the device, nonclinical testing may be developed based on information obtained from the EFS.
 - These nonclinical tests may be needed to support the initiation of a pivotal study.
- If the testing for the type of device is standardized and the testing is useful to predict clinical performance, the same testing may be required.

What are appropriate sources for leveraged information?

- Leveraged information can come from internal and external sources.
- Internal information includes testing conducted on prototypes or other device designs with similar characteristics or data from the device used for a different intended use.
- External information may include publicly available information, such as literature, or non-publicly available information, such as information obtained directly from a third party regarding a similar device.

Do I have to do all of the testing usually required to evaluate basic safety, such as all of the biocompatibility testing?

- It will be necessary to address all of the aspects of basic safety; however, it may not be necessary to conduct all of the testing that would be needed to support the approval of a pivotal study.
- In general, it is good practice to list all of the testing that would ultimately be required and explain how what the intent of the testing is being addressed for the EFS.

What are the review timelines?

EFS PRE-SUB

- There are no required timelines for EFS Pre-Subs.
- The goal is to communicate major issues as they are identified.
- The target for scheduling a meeting with a sponsor is within 60 days of receipt of the Pre-Sub, with feedback provided within 45 days of receipt of the Pre-Sub to allow for adequate preparation for the meeting.

EFS IDE

- There are not unique timelines for an EFS IDE; however, the review should be more interactive, reducing the time needed to address potential concerns.
- Also, the EFS guidance describes new methods to allow for timely device and clinical protocol modifications.

Where can I find additional information?

- Please contact the EFS Representatives with any questions regarding the EFS Program.