

An Early Feasibility Study Playbook Resource

The EFS–FDA Engagement Checklist

About this checklist

This checklist is intended to serve as a practical planning and readiness tool for sponsors and innovators developing medical devices under the FDA Early Feasibility Study (EFS) Program. It is not a regulatory requirement, but a structured guide to help teams think strategically about when, why, and how to engage FDA throughout early development.

Overall, this checklist is designed to reduce avoidable regulatory friction, improve the quality of FDA interactions, and increase the likelihood that EFS data meaningfully informs later-stage development, while maintaining patient safety and regulatory rigor. It reflects common challenges observed across early device programs and provides a shared framework for sponsors, sites, and regulators to align expectations.



This checklist will help teams:

Clarify/acknowledge the role of EFS in the overall development strategy

The checklist prompts sponsors to define what key uncertainties the EFS is meant to address, and how early data will support downstream decisions, including pivotal study design.

Plan proactive, continuous FDA engagement

The checklist reinforces the importance of engaging FDA early and often, particularly before committing to costly or long-lead testing, and ahead of major regulatory milestones such as IDEs, IDE supplements, or Breakthrough Device Designation requests.

Prepare for high-quality pre-submission interactions

The checklist outlines the core elements FDA reviewers benefit in seeing during early discussions, including clinical context, device evolution, testing strategies, risk mitigation approaches, and how EFS fits into the broader development lifecycle.

Strengthen technical and clinical rationales

By prompting teams to justify testing strategies, protocols, and acceptance criteria, and to reference applicable FDA guidance and standards, the checklist provides guidance for preparing comprehensive submissions.

Promote effective regulatory communication practices

The final section emphasizes principles that consistently improve FDA interactions, such as avoiding assumptions based on precedent, clearly telling the device development “story,” and maintaining continuity and documentation across review cycles.



Early Feasibility Studies (EFS) FDA Engagement Checklist

Use this checklist as a planning and readiness tool for FDA interactions during medical device development.

1. Clarify/Acknowledge the Goals of EFS

- Identify insights needed to further device development
- Use EFS to de-risk a future pivotal clinical study
- De-risk overall investment in device development

2. Engage Early & Often With FDA

- Obtain understanding of FDA expectations for EFS IDE, pivotal IDE supplement, and future marketing applications
- Engage before completing expensive or long-lead testing
- Engage prior to major submissions (IDE, IDE supplements, Breakthrough Device Designation request)
- Plan for iterative data needs across development stages

3. Establish Context for Pre-Submission Discussions

- Define clinical context and unmet need
- Describe device design concept and evolution

4. Address Protocols & Rationales Under Pre-Submissions

- Outline device evaluation strategy, that is, justify selection of tests, parameters based on in-vivo conditions, sampling and sample sizes, and acceptance criteria, as well as clinical risk mitigation strategies, referencing relevant FDA guidances and voluntary standards
- Describe bench testing, biocompatibility, animal studies, sterility, packaging, and shelf-life plans
- Describe transition plan from EFS to later-stage studies with respect to non-clinical testing, including a description of how testing will be leveraged across development stages
- Identify long lead-time or unique testing needs and submit associated protocols
- Summarize prior clinical experience and proposed EFS clinical study synopsis

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