Investigational Device Exemption (IDE)

for Digital Health Products

Digital Health Regulatory Pathways

What is the purpose of an IDE?

An investigational device exemption (IDE) allows an **investigational device** to be used in the US for a clinical study in order to collect safety and effectiveness data. Clinical studies are most often conducted to support an FDA Premarket Application (PMA). A small percentage of 510(k)s also require clinical data to support the application. Investigational use of a device also includes clinical evaluation of certain modifications or new intended uses of legally marketed products.

What is an investigational device?

An investigational device is a medical device which is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the product.

When is an IDE required?

An innovator or an investigator is required to submit an IDE application if:

- They intend to use a device with significant risk in a clinical investigation/study,
- They intend to conduct an investigation that involves an exception from informed consent, or
- The FDA notifies them that an IDE application is required for an investigation.

What are the overall requirements of investigational devices?

The clinical evaluation of digital health products that haven't been cleared for marketing (or commercialized) requires:

1. An IDE approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by the FDA.
2. Informed consent from all patients.
3. Labeling for “investigational use only.”
4. Monitoring of the study.
5. Required records and reports.

Learn more about the IDE application process.

Who should apply for an IDE?	An innovator conducting a clinical trial is responsible for submitting the IDE application to the FDA and getting an IRB approval before the study can begin. **Companies outside the US** who want to conduct a clinical study in the US must have a US sponsor. In some cases, the clinical investigator may wish to submit an IDE and would therefore also act as the sponsor of the study.
When should one apply for an IDE?	IDE study approval should be obtained **before** enrolling patients at the study site. Each site must have approval from the reviewing IRB for that site prior to beginning the study.
What are categories of investigational devices and IDE regulatory requirements?	All investigational devices fall under one of these categories: • Significant Risk (SR); • Nonsignificant Risk (NSR); or • IDE Exempt. Investigational devices under the IDE regulation are subject to different levels of regulations depending upon the level of risk: • **Significant risk (SR)** product studies must have an FDA approved IDE application and an IRB approval before the start of the investigation [*under 21 CFR 812*]. • **Non-significant risk (NSR)** product studies need to follow abbreviated IDE regulations that require only IRB approval before the start of the investigation [*under 21 CFR 812.2(b)].* • Product studies where the products can also be **exempt from the IDE regulations** [*under 21 CFR 812.2(c)].* Learn more about products with significant risk and non-significant risk, and products that are exempt.
When is my product exempt from IDE regulations?	A product is considered exempt from IDE regulations for the following reasons: • The product was in commercial distribution before 5/28/76 • The product is determined by the FDA to be 'substantially equivalent' to a device in commercial distribution before 5/28/76 • The product is a diagnostic product that: ○ is noninvasive,

	○ does not require an invasive sampling procedure that presents significant risk, ○ does not introduce energy into a subject, and ○ is not used as a diagnostic procedure without the confirmation of another medically established diagnostic product or procedure. • The product is used for consumer preference testing or for any test that is not intended to determine safety or effectiveness and does not expose subjects to risk • The product is used exclusively for veterinary indications • The product is to be shipped exclusively for research on laboratory animals • The product is a custom product, unless it is used to assess safety or effectiveness for commercial distribution Learn more.
What is an early feasibility study?	An early feasibility study (EFS) is a limited clinical investigation of a device early in development. It typically: • enrolls a small number of subjects; • is used to evaluate the device design concept with respect to initial clinical safety and device functionality; and • may guide device modifications.
How long does the process take?	An IDE application is considered approved 30 days after it has been received unless the FDA informs the sponsor otherwise.
What are the outcomes one can expect during the IDE process?	• The FDA will acknowledge the receipt of the IDE application (on the same day the application is submitted). The FDA will then either: ○ Approve the application, ○ Approve the application with a condition (the innovator must reply for the process to proceed), ○ Disapprove or withdraw approval of an IDE application, or ○ Implement a “clinical hold,” prohibiting the innovator from conducting the investigation. Learn more.

Where can I find IDE regulations and guidelines?	• List of regulations pertaining to the IDE process. • Comprehensive list of all clinical trial and IDE guidance documents. • For all other IDE related topics, learn more here.
Where can I find IDE reports and records?	IDE reports innovators must submit to the FDA. Innovators must also maintain accurate and complete **IDE records** related to any ongoing investigation. Learn more.
Where can I find FAQs about the IDE process?	Check out the most Frequently Asked Questions (FAQs) about the IDE process here.

Access DiMe's Digital Health Regulatory Pathway Resources

Identify your regulatory pathway

Build your regulatory strategy

Interact with regulators