

Understanding Medical Devices: **Clinical Evaluation** vs. **Clinical Investigation**

You know by now what a medical device is; you've seen them, you've read about them, they stand to be one of the greatest medical inventions of our time. But, how does it come to life? What processes are involved when placing a medical device on the market?

A medical device follows a detailed set of procedures before it's rolled out to the market. This includes clinical evaluation, clinical investigation, and a clinical development plan. These steps are absolutely vital, to make sure that the device being rolled out to the market is safe to use and does what it promises to do. Today, we're going to tackle two of these: **clinical evaluation** and **clinical investigation**.

Seeing the entire process visually can help you further understand it. But what do all these terms mean exactly? Let's dive into them further.

Are clinical investigation and evaluation the same thing?

It might happen that you'd be inclined to interchange these two terms but doing so would be wrong. Both terms are very different and refer to different stages in the process. Let's have a look at them separately.

What is clinical evaluation?

All relevant clinical data regarding a device is collected and assessed. Clinical data is all the information regarding the safety and performance of a medical device. It can be gathered through clinical investigations or available studies in scientific literature that is related to the medical device in question.

Essentially, the clinical data collected during this stage shows whether or not the device meets all regulatory requirements. It verifies the safety and performance of a device when it is used. This also helps determine whether or not a medical device needs to go through a clinical investigation. Any manufacturer that wants to bring a medical device onto the market, must have a completed clinical evaluation.

But what happens when there isn't enough clinical data available?

What is clinical investigation?

Simply put, when a device needs to go through a clinical investigation, this means that it needs to go through a human trial to test the safety or performance of a medical device. These are necessary for example, when a device:

- Has a new purpose that is not yet on the market
- Has new functions that has not yet been seen

Has been modified and there's a residual risk on the performance of the device or the modification has possibly affected the safety of the device

What is the difference between clinical evaluation and clinical investigation?

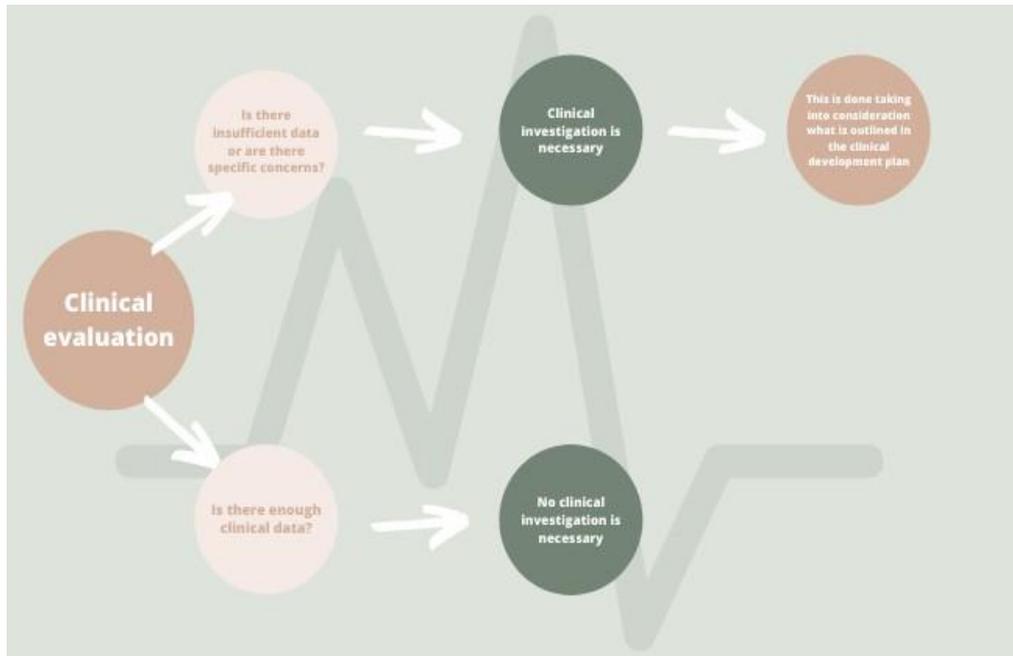
A clinical evaluation is crucial - a medical device cannot be put on the market without one. It follows a well-defined procedure, considering the critical evaluation of available scientific literature and the results of available clinical investigations.

So then, what is the relationship between the two?

These two terms are inherently linked. A clinical evaluation plan includes a clinical development plan, which then also involves the clinical investigation plan. A clinical investigation must be done in line with the plan laid out in the clinical evaluation. This includes:

- The reasoning behind the investigation
- The endpoints
- The variables

Let's have a basic view of this relationship (including clinical development plan for better understanding):



As you can see, a clinical investigation relies on the information set out in the clinical evaluation plan overall. All these plans must hold clear reference to each other. Consistency is essential for accurate execution to bring a medical device onto the market. Although keep in mind that this is a very simplified look at an otherwise complex and intricate system.

Understanding the full procedure of clinical evaluation and clinical investigation is vital to making sure each step is adhered to. However, it's also complex and can be a lot to take in all at once, which is why breaking down various aspects of it can be helpful. If you need any help with [training](#) or if you have any questions, feel free to [contact](#) Rianne Tooten.