4C Close-up – Insights into ...

Date: 29-Nov-2023 04.00 pm - 05.00 pm

Venue: Online

Costs: fee-based

Type: Webinar

Organiser: Medical Innovations Incubator GmbH

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Language: English

Links: ☑ to the event ☑ to the registration

4C Close up – From planning, to approval, to implementation of a clinical study

For medical devices and IVDs to be CE marked, their safety and performance must be demonstrated and supported by clinical data. In the case of innovative devices, there is usually too little clinical data available in the literature and therefore one has to conduct own clinical studies.

But how do I start planning a clinical study? Which documents do I need? How do I communicate with the ethics committee and the competent authorities, such as BfArM? What do I have to keep in mind when coordinating the study?

Join us for our next 4C Close-up webinar with Janina Clasen from Skinuvita. She will provide practical insights into the planning, approval process and coordination of their multi-center clinical study for their new medical device to prove its safety and performance. Together with our startup coach Henrike she will discuss her key learnings.

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