CHRU Besançon
centre hospitalier régional universitaire

CIC B
Centre d'Investigation Clinique de Besançon
INSERM CIC 1431

DinaMic
clinical evaluation of MD

CLINICAL EVALUATION OF MEDICAL DEVICES

Your needs

- Are you developing a new medical device?
- Are you currently implementing a transition plan to the new European regulatory framework?
- Are you extending the indications of your medical device?
- Are you in need for a clinical study?

Our Know-how

CERTIFIED
EURO-QUALITY SYSTEM
ISO 9001

Located within Besancon University Hospital, the Clinical Investigation Center (CIC) is supported by the "Institut national de la santé et de la recherche médicale" (Inserm) and Ministry of Health (DGOS)

Inserm

Navigating the process of obtaining/maintaining the CE mark for your medical device can be difficult without a partner with research experts to assist you

We can provide support for the clinical evaluation of your medical device

Litterature review

Comprehensive review of current state of the art with medical experts

Design of clinical study / trial*

- Feasibility and trial promotion
- Synopsis and protocol
- Estimate of study costs, tailored to your situation and complexity of the study

Implementation of clinical investigation*

- Preparation of study documentation (protocol, information to patient, consent, case report form…)
- Writing/review of study protocols and documents for regulatory compliance
- Preparation of regulatory submissions
- Coordination and follow-up of the trial
- Monitoring
- Datamanagement, statistical analysis
- Clinical study report, publications

* *pathophysiological studies usability testing, prototype studies, pre- and post-market investigations…*

- In collaboration with the clinical research and innovation office (DRCI)
- At the interface between **care departments and clinical research experts**: physicians, scientists, methodologists, clinical research associates, data managers, biostatisticians
- ISO 9001 certified

TELL US YOUR NEEDS !

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… we will provide you with personalized solutions

OUR PARTNERS

UBFC Université Bourgogne Franche-Comté

EFS

femto-st Sciences & Technologies