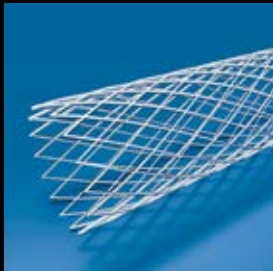


# Guarantee the validity of your clinical results



EXPERTS  
 **evamed**  
The evaluation of medical devices

# A full support to guarantee the validity of your clinical results




**YOUR MEDICAL DEVICE EVALUATION:**

- ✓ Interventional study
- ✓ Observational study
- ✓ Register
- ✓ Post-marketing study

**Why Evamed ?**

- ✓ Medical devices expertise
- ✓ Ergonomy
- ✓ Reactivity and availability
- ✓ Guarantee the validity of your results



	<b>+ Additional expertise</b>
	<ul style="list-style-type: none"> <li>CE-mark files</li> <li>Literature review</li> <li>Study management</li> <li>On-site or centralised monitoring</li> <li>Study report</li> <li>Medical writing</li> </ul>

# 1

## STUDY DESIGN

### Protocol

- Protocol writing
- Sample calculation and writing of the statistical paragraph
- Case report form design

### Regulatory affairs

- Management of regulatory filings

- ✓ Respect of Good Clinical Practices
- ✓ Compliance with regulations
- ✓ Clinical and scientific expertise

# 2

## DATA-COLLECTION

### eVal-CRF

#### Functionalities:

- Ergonomic and user-friendly interface
- Automatic controls on data
- Automatic score calculation
- Online randomization
- Imaging management
- Interactive schemes
- Mobile interface compatibility
- Mail alerts
- Queries management
- Advanced monitoring functionalities
- Amendments traceability : audit-trail
- Online statistical analysis module

#### Included services:

- Support by an experienced data-manager
- Users training
- Hotline and technical support
- Software maintenance
- Secured data hosting

#### Optional Modules:

- **eVal-PRO** : online clinical data entry by patients (from home or from waiting room)
- **eVal-CONFIG** : autonomous configuration by the sponsor

- ✓ Fast and simple data input for investigators
- ✓ Save time for monitoring
- ✓ Data reliability
- ✓ Cost-reducing
- ✓ Compliance FDA 21 CFR part 11
- ✓ Secured hosting

# 3

## DATA QUALITY CONTROL

### Data management

- Writing of the data-management plan
- Programming of coherence controls
- Regular sending of incoherences listings

- ✓ Time saving on incoherences detection
- ✓ High data quality

# 4

## DATA ANALYSIS

### Statistics

- Writing of the statistical analysis plan
- Data-analysis
- Outcome interpretation
- Writing of the statistical report

- ✓ Compliance with standards
- ✓ Time-saving
- ✓ Results reliability

# A medical device expertise to guarantee the validity of your clinical results



## About Evamed

Created in 2005, Evamed is composed of experts in medical devices clinical evaluation : physicians, data-managers, IT specialists, methodologists, medical writers.

### Evamed's values:

- ✓ Customer and user satisfaction
- ✓ Product and process quality improvement
- ✓ Innovation and enthusiasm

Evamed has ISO 9001 certification, is accredited CIR and training provider.



## NEARLY 100 STUDIES RUN BY EVAMED

### Evamed's studies today:

- observational studies
- interventional studies
- post-marketing studies and registers
- studies duration between 6 months and 20 years
- between 3 and 1200 centers by study
- between 40 and 20000 patient files by study
- centers in 27 countries : United-states, Germany, Italy, Belgium, United Kingdom...



## EXAMPLES OF STUDIED DEVICES

### Orthopaedics

- Cups for arthodesis hand surgery
- Plates for tibial osteotomy
- Hip prosthesis
- Knee prosthesis
- Total ankle replacement prosthesis
- Resorbable screws
- Lumbar cages
- Knee external prosthesis
- Femoral nails
- Ligamentoplasty
- Bone tumours follow-up

### Cardiology

- Biodegradable annuloplasty rings
- Pacemakers
- Telecardiology systems
- Defibrillators
- Stents

### Ophthalmology

- Intraocular lenses
- Contact lenses
- Intraocular implants

### Urology

- Parietal implants
- Urinary incontinence tapes
- Textile prosthesis
- Surgical glues

### Other devices

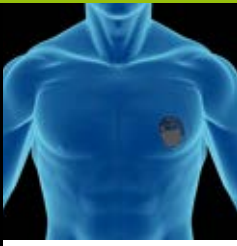
- Compression garments
- Breast compression systems
- Dialysis
- Neuromodulation systems
- Sleep apnea devices
- Dental implants

EXPERTS



# evamed

The evaluation of medical devices



## Testimonials

# Testimonials

« Evamed is **reactive**, has met our expectations and dealt with issues in a **quick and efficient** manner. »

**Isabelle LEFEBVRE**

Marketing Director  
COUSIN Biotech

« We met other companies offering an eCRF, but Evamed's solutions seemed more efficient, more **ergonomic** and with advanced functionalities.

We chose Evamed for its technical assistance, and **its cost-effectiveness**. »

**Bénédicte LÉ**

Clinical Research Manager  
BIOTRONIK France

« As clinical manager, I used Evamed's eCRF during 4 years. You can manage your clinical studies and **queries easily**. The Evamed team is **reactive** and **always available to help you find the best solutions**. »

**Claire CISTERNI**

Previously clinical manager THT,  
now consultant

« I am very pleased with Evamed's services and appreciate our strong business relationship. Evamed shows reactivity, **internal traceable procedures** and provides me with all the **answers and advice** I need. »

**Hugo RYCKEBUSCH**

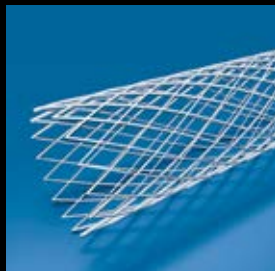
International Medical Affairs Manager  
PORGES - COLOPLAST

« Evamed's strength is a user **friendly tool, highly customizable**, under our own control. It helped us to **optimize our project management**. »

**Nicolas CANOT**

Clinical Research Director  
BIOTRONIK France

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of your clinical results**



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