WE REPRESENT CONTINUITY

ARTIMED®, founded in 1998, guides a portfolio of customers from the national and international business field of clinical research. Over the years, the remit has been expanded and extended continuously. This enables us to offer solutions for the following areas in the field of clinical research:

_Clinical Study

_Post Market Clinical Follow-up studies

_Clinical Evaluation in accordance with MEDDEV 2.7/1 rev. 4

_Publication of Clinical Data

_Seminars on the topics MPG / AMG and ICH-GCP / DIN EN ISO 14155

_Clinical Quality Management

Rheumatology
Onkology
Neurology
Ophthalmology
Nephrology
Intensive-Care Medicine
Dermatology
Diabetology
Cardiology
Orthopedics
Psychiatry
General- und Plastic Surgery
Endocrinology

WHAT CUSTOMERS SAY ABOUT ARTIMED®

„Guidelines compliant implementation of clinical evaluations for our medical devices with extremely professional results, this is ArtiMed Medical Consulting GmbH“.

Major international manufacturer in the medical technology

„If you are looking for a dedicated team for project management and monitoring of clinical studies, then ARTIMED Medical Consulting are the right choice!“

Leading manufacturer of medical devices in cardiology

„Competent, first-hand expertise in a relaxed and enjoyable atmosphere - we can recommend the ARTIMED Medical Consulting GmbH.“

Leading organiser of advanced seminars

Dr. med Markus Hahn
CEO

ARTIMED® Medical Consulting GmbH
Friedrich-Ebert-Straße 25
34117 Kassel / Germany

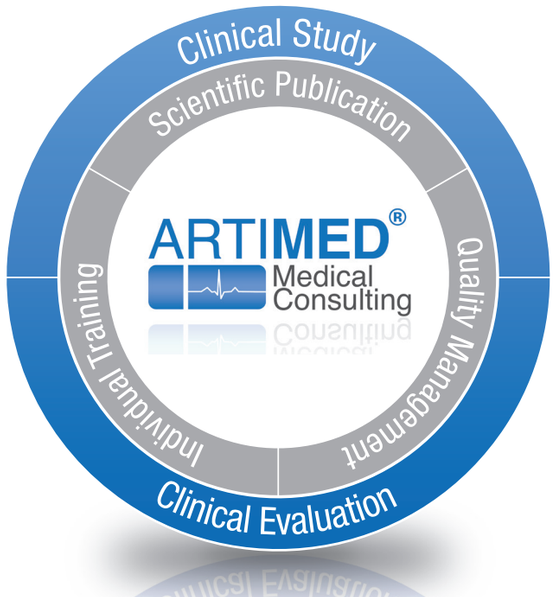
Phone.....00 49 561 7050815-0
Fax.....00 49 561 7050815-9
Mail.....info@artimed.de
Web.....www.artimed.de

ARTIMED® Medical Consulting

Your professional Contact in the field of Clinical Research

EVERYTHING FROM ONE SOURCE

We offer you the proper execution of clinical studies from design through to evaluation and publication.
In accordance with the new MEDDEV guidelines, you will receive assistance in the preparation of clinical evaluations.
Certified training and seminars ensure that your projects are realised by qualified personnel with the necessary know-how.
The publication of your data in high-quality medical journals ensures that the scientific community is well informed about your medical devices.



CLINICAL STUDY

Through our expertise and experience we can help you to manage the creation and submission of study documents to the relevant authorities and Ethics Committees.
We will assist you in planning, initiation and implementation of clinical studies. Our in-house SOPs guarantee a harmonized and structured approach to all stages of a clinical study in accordance with applicable laws, regulations and standards (ISO 14155).

_SELECTION of STUDY SITES

_PREPARATION and SUBMISSION of study documents

_COMMUNICATION with the authorities and ethics committees

_INITIATION, MONITORING and CLOSE-OUT of the study sites

_AUDIT

_DATA MANAGEMENT and STATISTICAL ANALYSIS

_CLINICAL STUDY REPORT

CLINICAL EVALUATION

Since June 2016, the new MEDDEV guideline sets higher requirements on the implementation of clinical evaluations. Furthermore, the fourth MPG amendment states that manufacturers of medical devices are required to setup a clinical evaluation for all medical devices and that these are to be updated at regular intervals.
Benefit from our experience with more than 300 written clinical evaluations. Our self-developed form system fully reflects the current guidelines and ensures that the requirements are met at a reasonable cost.

_Conduct clinical evaluation according to the new MEDDEV GUIDELINE

_REGULAR UPDATES

CLINICAL QUALITY MANAGEMENT

We will assist you in the customisation of your clinical quality management accoring to the new requirements of the fourth MPG amendment and in accordance with DIN EN ISO 14155:

_PREPARATION of SOPs for clinical trials

_Customisable to meet your requirements

CERTIFIED TRAINING AND SEMINARS

Do your employees require training regarding the changed general conditions? We conduct individual training sessions that are based on your specific requirements and cover the following topics:

_MPG / DIN EN ISO 14155

_AMG / ICH-GCP

_Investigator TRAINING

SCIENTIFIC PUBLICATION

You wish to publish the results of your clinical study or are looking for assistance in writing scientific articles? We assist you in the search for a suitable journal, prepare text and graphics and ensure that the data is presented for maximum profit for your business.

_PUBLICATION of study results

_ASSISTANCE in writing a scientific article