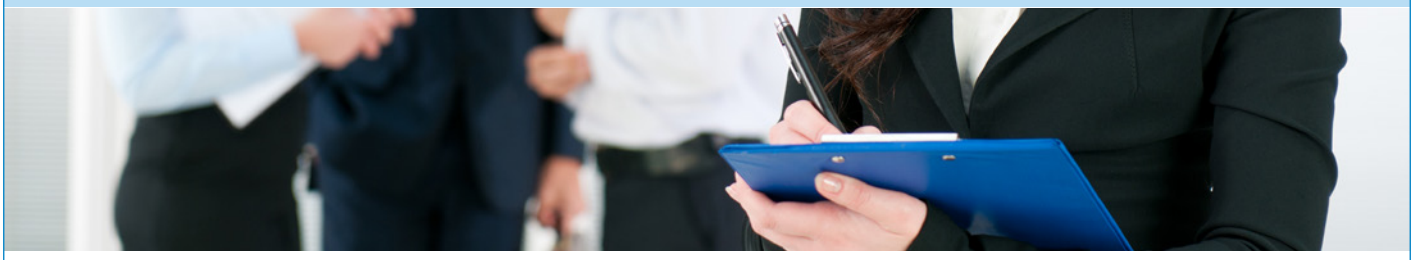
ACM
ALLIED CLINICAL MANAGEMENT



Allied Clinical Management GmbH, a Berlin based CRO, conducts clinical trials on behalf of pharmaceutical and medical device sponsors.

ACM has currently two vacancies for a

Medical Writer

for early phase clinical trials.

The Medical Writer (m/f) as an expert and a project- / team-member will have to:

- guarantee timely and accurate creation of relevant Biomarker/Pharmacometrics documents in cooperation with the Biomarker/Pharmacometrics expert. Coordination of all submission relevant reports and documents aligned with project goals and according to international and regulatory standards.
- be the first point of contact for topics related to Biomarker/Pharmacometrics.

The Medical Writer will be:

- assigned directly to the Head of Medical Writing.
- in a managerial position, responsible for Medical Writing Biomarker/Pharmacometrics.
- working in an inter-divisional collaboration within the project team to internal and external team members (e.g. Project Lead, Clinical Operations Lead, Biomarker/Pharmacometrics, Pharmacodynamics, Pharmacokinetics, Data Management, Bioanalytics, Biometrics, Programming, GCP-Auditing, Regulatory Affairs, external Medical Writing)– Contact partner for external medical writers.

The Medical Writer

- works independently on the creation of Biomarker/Pharmacometrics documents for approval reconciling with the following documents: biometrics tables, statistics, written bodies of reports, written abstracts

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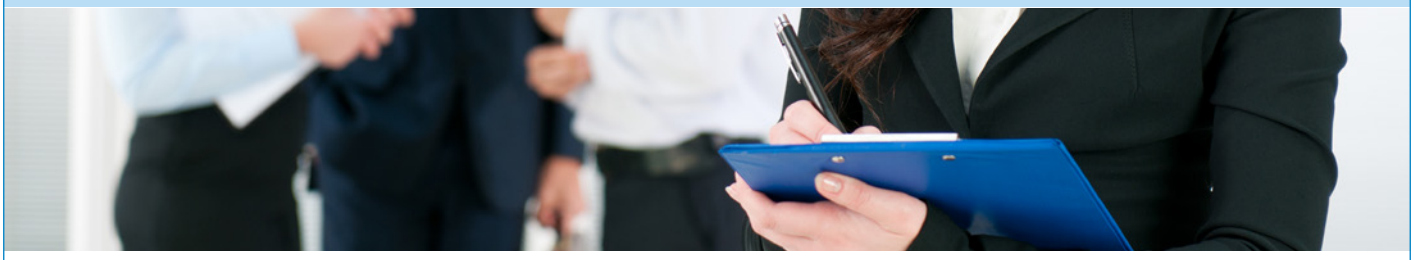

Medical Writer

- supports functional experts in creating submission relevant documents, presentations and publications utilizing knowledge of the following areas: Biomarker/Pharmacometrics and Medical Writing
- uses proactive communication with the Biomarker/Pharmacometrics expert and head of the medical writing team in order to create reports/abstracts, discuss related content and to finalize the report/abstract according to regulatory timelines
- acts as first point of contact for all Biomarker/Pharmacometrics issues
- checks overall quality, correctness, plausibility, internal and external standards and guidelines before finalization of documents
- checks submission relevant project/study documents for accuracy, plausibility and adherence to company/international standards and guidelines
- works proactively in expert teams to develop standards for Biomarker/Pharmacometrics
- contributes to the maintenance of the global documentation system, especially in the area of Biomarker/Pharmacometrics
- executes technical quality checks of the protocol
- supports medical writer regarding content and process questions

Experience:
At least five years of experience within the pharmaceutical industry (at least two years working experience in the field of medical writing, inclusive).
Excellent knowledge in the field of Biomarker/Pharmacometrics.
Substantial EDV experience.
Team orientated working philosophy in an inter-divisional atmosphere with complex working structures.
Experienced with medicinal and statistical terminology.

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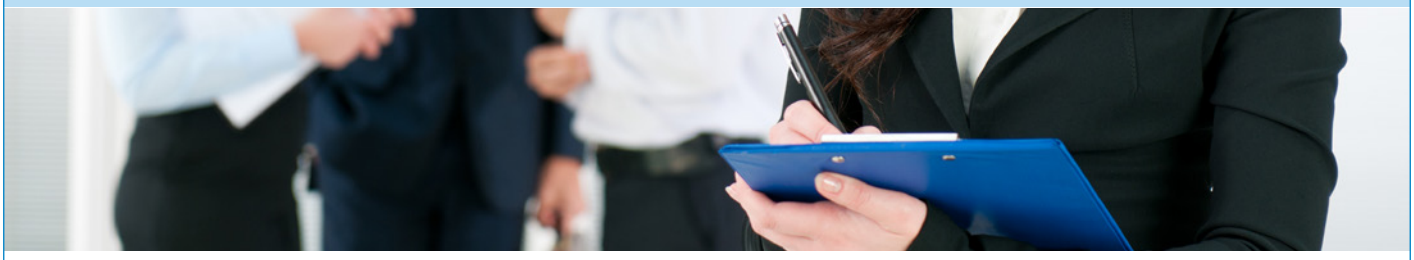

Medical Writer

Ability to work with a complex amount of data and to distinguish and identify and describe relationships among data.
ICH-GCP, knowledge of clinical trial conduct from a variety of operational functions.

Degree:
Scientific or medical degree, university degree or equivalent.
PhD in a natural science or a medical degree will be given preference.

Languages:
Excellent written English skills are a must. Native speakers of English will be given preference.
Knowledge of written and spoken German.

Location:
Berlin or greater Cologne-Düsseldorf region.

Travel:
Occasional travel within Germany may be necessary.

Start:
Immediately.

Conditions:
Full-time / 40 hours per week,
compensation negotiable.

Required Documents:
CV, certificates.

Please respond to:

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