

# Partnering Invitation for Clinical Trial Management in Germany

**Services offered by  
Mednavigator and moco  
complementing your needs**

# Who we are

## Almut Malone



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## Holger Hoffmann



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# Who we are

## Short profile of Almut Malone

Dr. med. vet; Abundance of Experience with Monitoring since 1991, Freelance since 1996, Sourcing of IMP, Supply Management since 2001, Clinical Study and Project Management since 2006, Temperature-controlled IMP Logistics since 2008.

Currently designated applicant for submissions in Germany of cancer, immunology, pediatrics and rare disease studies, feasibility, investigator search and site set-up, vendor evaluation and selection, budget negotiation, forecast and control, CRO and vendor oversight, optimization with significant cost savings, leading TCs with virtual teams across continents, project plan and implementation, co-monitoring, audit preparation and attendance.

Highly motivated and self-organized, stringent with quality, budget and timelines, high awareness in all areas and interfaces of clinical trials including IRT.

Fluent in English (father tongue) and German (mother tongue) with track record of translations for clinical trial documents.

## Short profile of Holger Hoffmann

Biologist; Started working as a CRA in May 2002 within a large CRO. Co-Founder of moco and started as a Freelancer in June 2006. Over time, covered increasing responsibilities, roles and a broad variety of indications: CRA, International Site Management, Contracts Negotiations and Management, Regulatory Affairs, Line Management, Leading Cross Functional Teams, Audit Preparation, Study Setup (ISFs, IMP, Essential Documents collection), Meeting Arrangements (F2F and virtual), Delivery of ICH-GCP trainings, Setup of a multinational disease registry trial with about 1000 patients in about 20 countries. Currently, Contracts Management in Germany, Austria and Switzerland for about 130 (+) contracts .

Strong communication skills. Following a customer-focused approach. Highly self-motivated and organized.

Fluent in German (mother tongue) and English. Basic skills in French.

# Who we are

## Key competences

### Mednavigator:

- Generation of ICFs
- CTA submissions
- EU GDPR trained
- Vendor selection
- IMP distribution
- Cold chain logistics
- Inspection preparation
- Translations Engl.-Ger.

### moco:

- Site selection / set-up
- Document collection
- Contract negotiations
- Vendor coordination
- Document proof reading
- TMF and ISF services
- Hiring of support staff
- Complete TC service

# Indication experience

- Cancer (breast, renal, colorectal, solid tumors, melanoma, prostate / bone metastases)
- Immunological (sepsis, MS, autoimmune diseases)
- Rare diseases (MPS II, A1P1 deficiency, Fabry)
- Pediatric diseases (hemophilia, growth hormone def.)
- Cardiovascular (all indications, including stents and cryotherapy, transplantation, cardiac shunts)
- Lung diseases (pneumonia, asthma, COPD)
- Brain (epilepsy, subarachnoidal aneurysma bleeding)
- Many other (insomnia, endocrine, medical devices)

# Why we are different

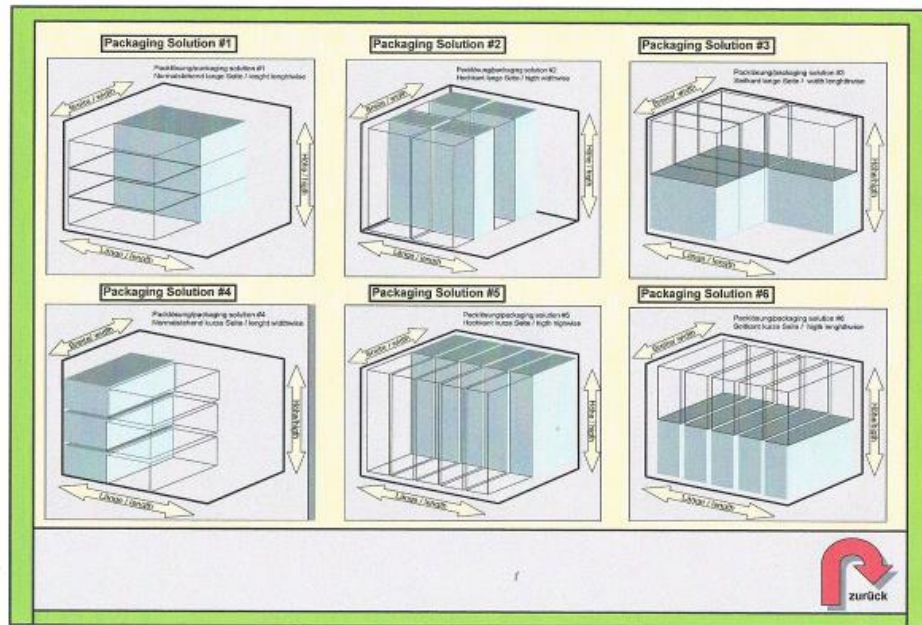
- We earn our money with constant effort to save expenses and optimize budgets for the sponsor
- Our turn-around times are faster than with any service provider working only with employees
- We have extensive experience with CROs and vendors to achieve realistic budget evaluation
- Our setting always considers back-up solutions
- If a project is too large for us, we let you know before and have multiple contacts for support

# Examples for cost savings

- Negotiated site fees of in total 14% (€ 2.3 million) below the medium assigned budget
- Saved € 0.7 million of vendor costs by comparing and reducing service packages to required limits
- Lowered already established distribution budget for phase 3 trial from € 2 million to € 800.000
- Prevented expenses of € 180.000 for one large IMP shipment to Israel by changing inner cartons
- Reduced courier costs with better calculation tool

# Example for cost savings

Make sure not to pay for shipping air



**Six sides of a box = 36 packing orientations**

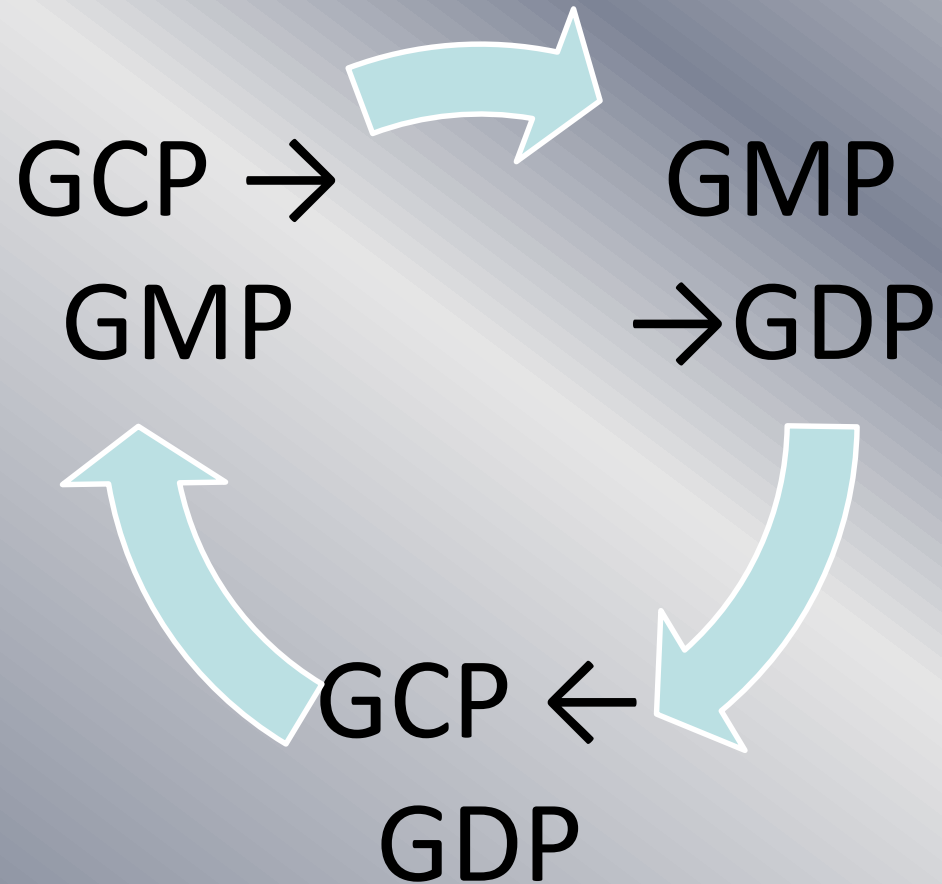


# What we do

## Start-up phase:

- Preparation of project kick-off meetings
- Protocol review, translation of synopsis
- Writing of project + other plans and local SOPs
- Generation/review of feasibility questionnaires
- Site identification and CDA collection
- Feasibility set-up and performance at German sites
- Determination of required resources (vendors, CRAs)
- Site selection visits and evaluations
- Set-up of local trial master file and investigator files

# We review and improve all interfaces



# What we do

## Initial phase:

- Obtain EudraCT number
- Vendor selection and evaluation
- Collection of essential documents from sites
- Quality check and updates of site documents
- Obtain clinical trial insurances (office in D required)
- Compilation of submission documents for CA and ECs
- Designated applicant to CA and ECs in Germany (with all initial submissions, additional requests, amendment filing, SUSAR reporting, periodic and annual reports)
- Notification of sites to local authorities

# What we do

## Set-up phase:

- Clinical trial registry (mandatory in US/EU)
- Vendor negotiations, contracts, set-up, manuals
- IMP label translation and regulatory check
- Logistics (IMP, laboratory, printing, couriers)
- Sourcing of study site equipment (if needed)
- User acceptance tests of electronic systems
- Define reporting forms and frequency to sponsor
- Consult on CRA and investigator meetings
- Perform required trainings
- Complete preparation of site initiation visits

# We know them all – We pick the best for each purpose

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# What we do

## Study conduct phase:

- Project and/or study management (including budget)
- Vendor management and issue resolution
- Extended site management (also on public holidays)
- Ongoing reachability for CRAs and site staff
- Medical management / interface to medical expert
- File maintenance and preparation for archiving
- Invoice management (authorities, ECs, sites)
- Supply management and stock/expiry-update oversight
- Remote monitoring and CRA/CRO/vendor oversight

# What we do

## As required during an ongoing clinical trial:

- SAE and SUSAR reporting and follow-up
- Review of site visit reports
- Co-Monitoring
- Audit preparation and back-office
- Authority inspection preparation and attendance
- Sourcing of additional personnel, also for sites (e.g. from „Flying Study Team“)
- Trouble shooting, e.g. in case of low recruitment
- Set-up of FAQ and CAPA documents

# What we do

## Study close-out phase:

- Closure notifications to CA/ECs and local authorities
- Review of IMP and supply reconciliation
- Organization of local IMP destruction
- Document review and preparation for archiving
- Final payments management (authorities, ECs, sites)
- Shipment of final reports to all relevant parties
- Contract terminations
- Review and submission of final study report
- Sourcing of external archiving solutions as required



# Additional services

- Supply management starting with optimized packaging design
- Sourcing of comparators and medical devices
- Complete set-up of temperature-controlled shipments with tailored shipping boxes, temperature devices and courier options
- Contribution to IRT set-up (access to expert)
- Interface review between IRT and logistics
- Distribution management according to GDP
- Support with handling deviations and recalls

# We chose what serves you best – on *every* level



# Additional services

- Submission of evaluation requests to the German Radiation Association (DRG)
- Applications to the Federal Institute for Radiation Protection (BfS)
- Attendance at CEC review meetings for sponsor
- Preparation of scientific advice meetings at BfArM, EMA or FDA
- Pharmacovigilance (with business partner if required)
- Cooperation with freelance experts in Austria and Switzerland

# Our price structure:

We don't have one (up front)!

First we have to understand what must be done.

Then we want to be thrilled with what we do.

You can count on our genuine interest to provide the best service for our clients - and the patients.

We prefer working on meaningful products.

If there are problems, we turn up with solutions.

With us you get fast access to a good network.

Our goal is to maintain longterm cooperation.

# We raise these babies until they fly



Hatching black redstarts



Restoring old motorbikes – here BMW R25/3 1954

*Try us – any free capacity usually fills very fast.*