#### **■ COMPANY PROFILE**



**Dr. Arman Notghi** *CEO*arman.notghi@notghi.com

# **History and Mission**

**Dr. Notghi Contract Research GmbH,** based in Berlin, is an independent full-service contract research organization. For over 20 years now, Dr. Notghi CRO has supported its clients in submission and conducting clinical trials and investigations. As full-service CRO we have also extensive experience of the regulatory requirements in pharmacovigilance and post-market surveillance. We offer our services to clients predominantly from Germany, Switzerland and Austria.

# Highlights

#### What we offer:

- Long-term relationships
- Services you can rely on
- Easy to contact, quick to respond
- Broad expertise for complex projects
- Ability to act quickly
- Competence vou can trust
- Precision with foresight

## **Training from Experts for Experts:**

Dr. Notghi Academy, as part of the Dr. Notghi CRO since 2010, is a certified educational institution specialised in training for the pharmaceutical industry.



#### Dr. Notghi Contract Research GmbH

Beuthstrasse 7 10117 Berlin, Germany

Tel. +49 30 206225-0 Fax +49 30 206225-100

E-Mail: info@notghi.com

BVMA Member since 2021 Audit passed in 2021





www.notghi.com

#### Services

### **Clinical Trials & Investigation**

#### **Project Management**

- Clinical Trial Feasibility
- Study Management
- Risk Management
- Training

# **Medical Writing**

- Investigator Brochure
- Study Synopsis
- Clinical Study Protocol
- Clinical Study Report
- Abstract / Publication

# Monitoring

- Centralized Monitoring
- On-site Monitoring
- Risk-based Monitoring approaches

#### **Data Management**

- CRF Design
- Database Set-up (EDC- and paperbased)
- Data collection, cleaning and coding
- Data base lock

# **Regulatory Affairs**

- Submission
- Communication with competent authorities and ethic committees
- Webposting
- Lay Language

#### **Drug Safety & Pharmacovigilance**

- Processing, Evaluation and Reporting of SAEs and SUSARS
- Literature Review
- Preparation of DSURs and PSURs

## Dr. Notghi Academy

# Site Staff Trainings

- GCP Courses for Investigators & Study Personnel
- Study Nurse Courses

#### **Postgraduate Trainings**

- Clinical Trials & Vigilance
- Life Science Management

# **In-house Trainings**

 Customized Pharmacovigilance & Clinical Trial Workshops



