PHARMALOG®

Institut für klinische Forschung GmbH

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Pharmalog – Philosophy

- Transparent
- Accurate
- Flexible
- Friendly

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Staff – Organizational Chart

You will profit from our privately owned company with short-decision-processes.

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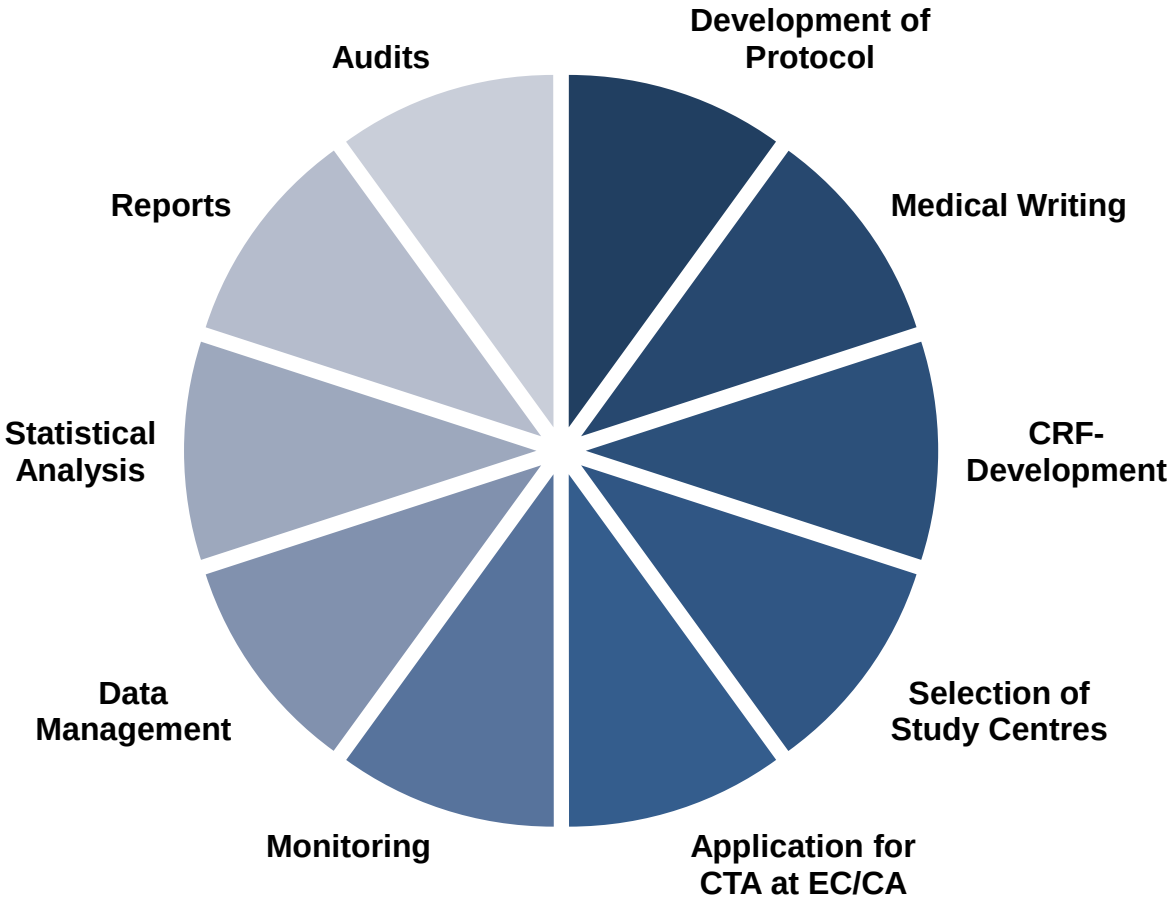
Scope of Service



We support you either as a Full Service CRO or with needed Sub-Services.

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We know Study Design

Study Preparation

Study Design

Clinical and Biometrical Concept

Medical Writing

Approvals (EC/CA)

Our CEO is a statistician with more than 25 years experience in pharma.

An individually adapted study design is a welcoming challenge for us.

We design the protocol to the trial's need, instead of combining modules.

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We know Project Management

Processing the Clinical Trial at the Sites

Recruitment of Sites

Training

Clinical Project Management

Our project managers are experienced in conducting clinical trials and monitoring of study sites.

Our eight project managers have a scientific or medical background. They are your contact persons and are dedicated to your clinical trial.

With our large pool of experienced investigators (hospitals and practices) we are able to recruit motivated study sites in time.

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We know Monitoring

Processing the Clinical Trial at the Sites

Monitoring

We have a consistent and well experienced team of seventeen CRAs.

Our internal CRA-trainer supports our monitors on regular basis.

In addition all CRAs are regularly co-monitored.

We implemented a quality circle for CRAs to offer a platform to exchange experiences.

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We know Data Management

Data Processing & Evaluation

Setup Database

Data-Entry/ - Validation

Statistical Plan

Statistical Evaluation

Query Management

We have three statisticians and six proficient data managers supported by data management assistants in our team.

The lead data manager will take care of your project from the beginning to the end and act as a competent contact person.

We prepare paper CRF or eCRF according to your requirements.

Our computerized systems are validated according to GAMP5.

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We know Reporting

Reporting

Writing integrated Study Report according to ICH-GCP

Our two medical writers develop your integrated study report in cooperation with biometrics department according to ICH E3 requirements.

We support you throughout the whole process of the publication of your clinical trials results.

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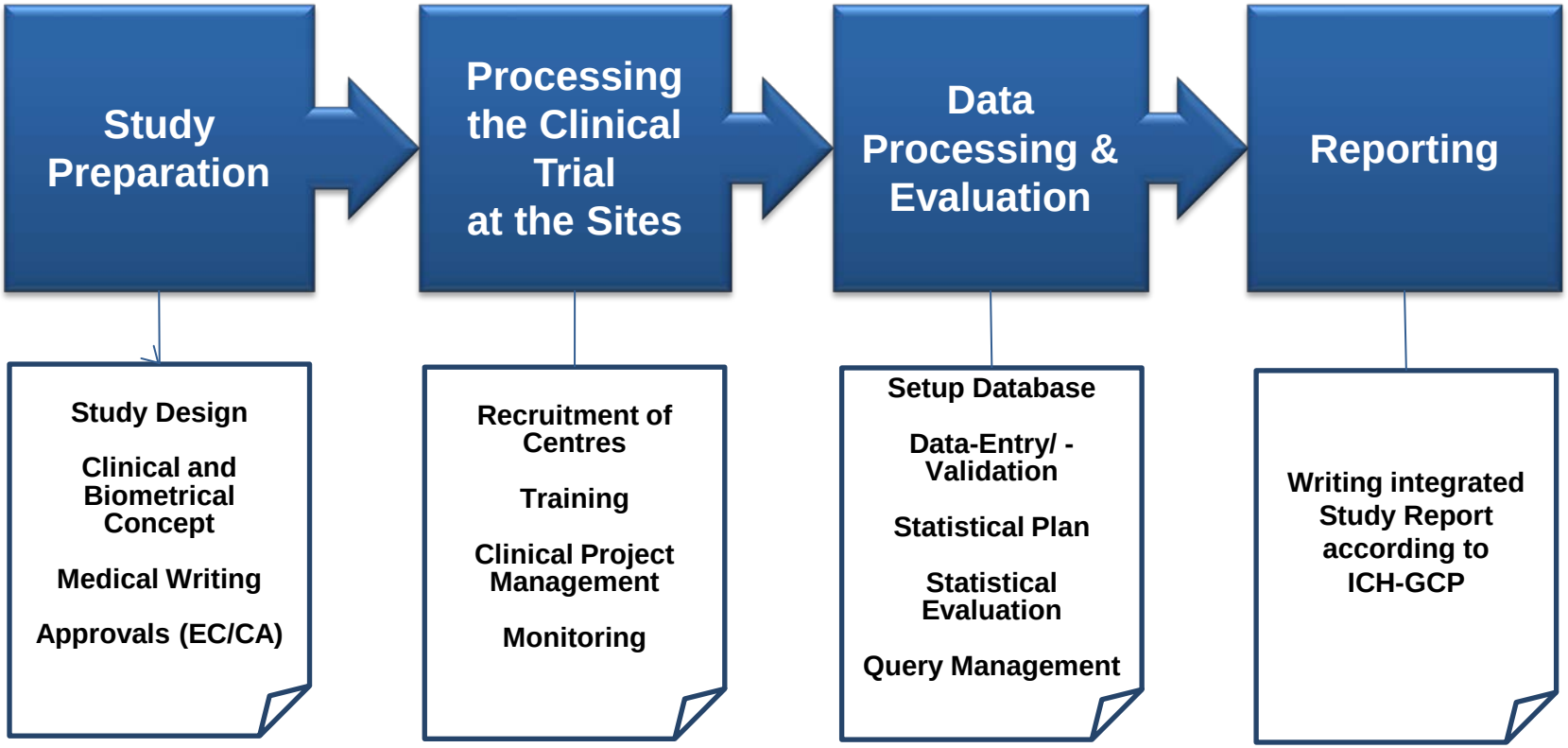
Transparency - Clear Processes



Controlled by QA Manager over all processes.

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We know Quality

Quality

SOPs

Verification and Documentation

Training

Continuous Improvement

Our quality control steps are constantly integrated in our processes.

All TMF-files are audited consequently.

We realize internal and external trainings for the whole team on regular basis.

We implemented an overall CAPA management system for our continuous improvement.

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Last Audits

Year	Internal Audits		Sponsor Audits	Inspections	Vendor Audits	
	Performed by Pharmalog - Staff	Instructed by Pharmalog			Performed by Pharmalog - Staff	Instructed by Pharmalog
2008	1 TMF	1 IT-System	1 System 2 Sites	1 TMF		1 System
2009	2 System 2 TMF	1 System 1 TMF	4 System 1 Site		4 System	
2010	2 System 4 TMF 2 Sites	1 FDA (mock) 1 TMF	8 Sites 1 TMF		11 System 3 Qualification visits	
2011	3 TMF	1 System 7 TMF 1 Data protection	2 Systems 1 BVMA 3 Sites	4 Sites	5 System 3 Qualification visits	1 System
2012	1 System 8 TMF	2 System (ISO) 1 TMF	3 System 4 Sites		2 System 3 Qualification visits	1 System
2013	2 Home office 3 TMF	1 System 1 Data protection 1 System (ISO) 1 TMF	1 System		5 System	

We are audited on regular basis by our sponsors and we audit our vendors in the same manner.

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Main Indications

FIELDS OF EXPERIENCE				
Cardiovascular	Oncology	Rheumatology and Pain	Dermatology	Phlebology
CNS/Psychology	Gynaecology	Genitourinary	Hormone-Replacement	Gastrointestinal
Metabolism	Respiratory	Ophthalmology	Paediatrics	Phytotherapeutics

More than 400 finished studies for more than 50 companies
Large pool of experienced study centres – clinics and private practices

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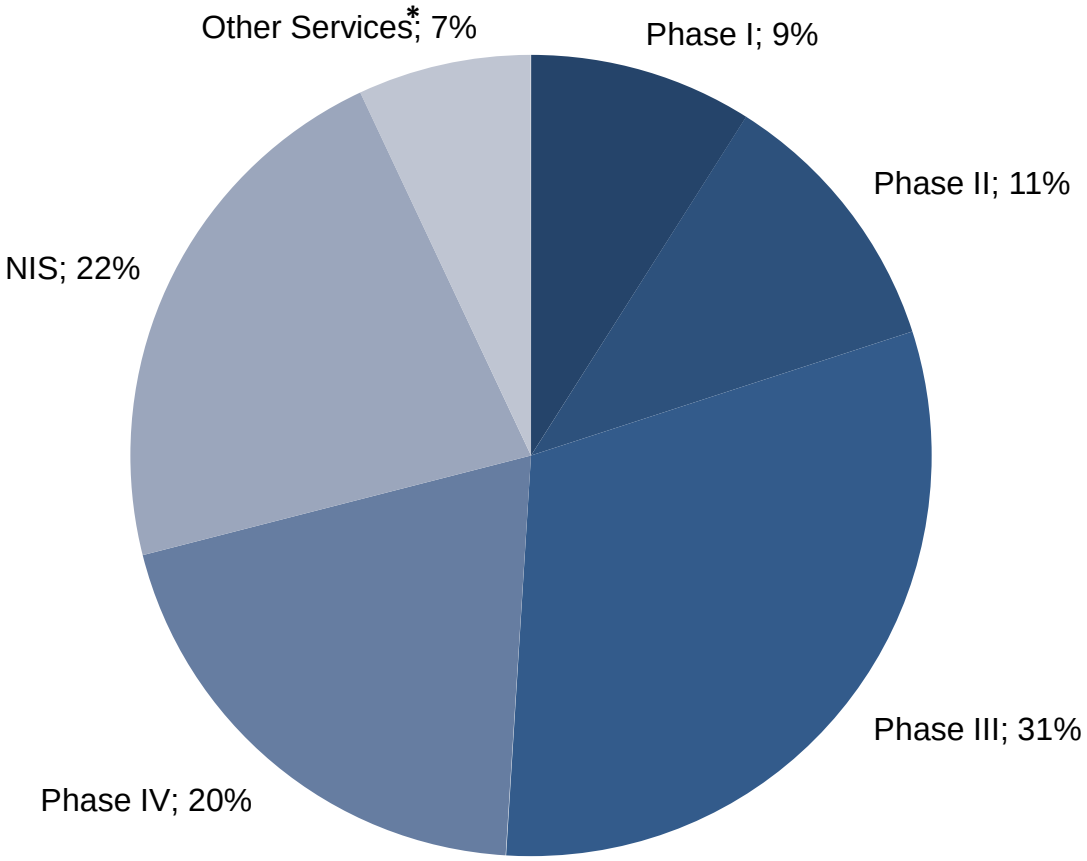
Overview Study Phases (last 10 years)



* Audits
Trainings
Consulting
Publications

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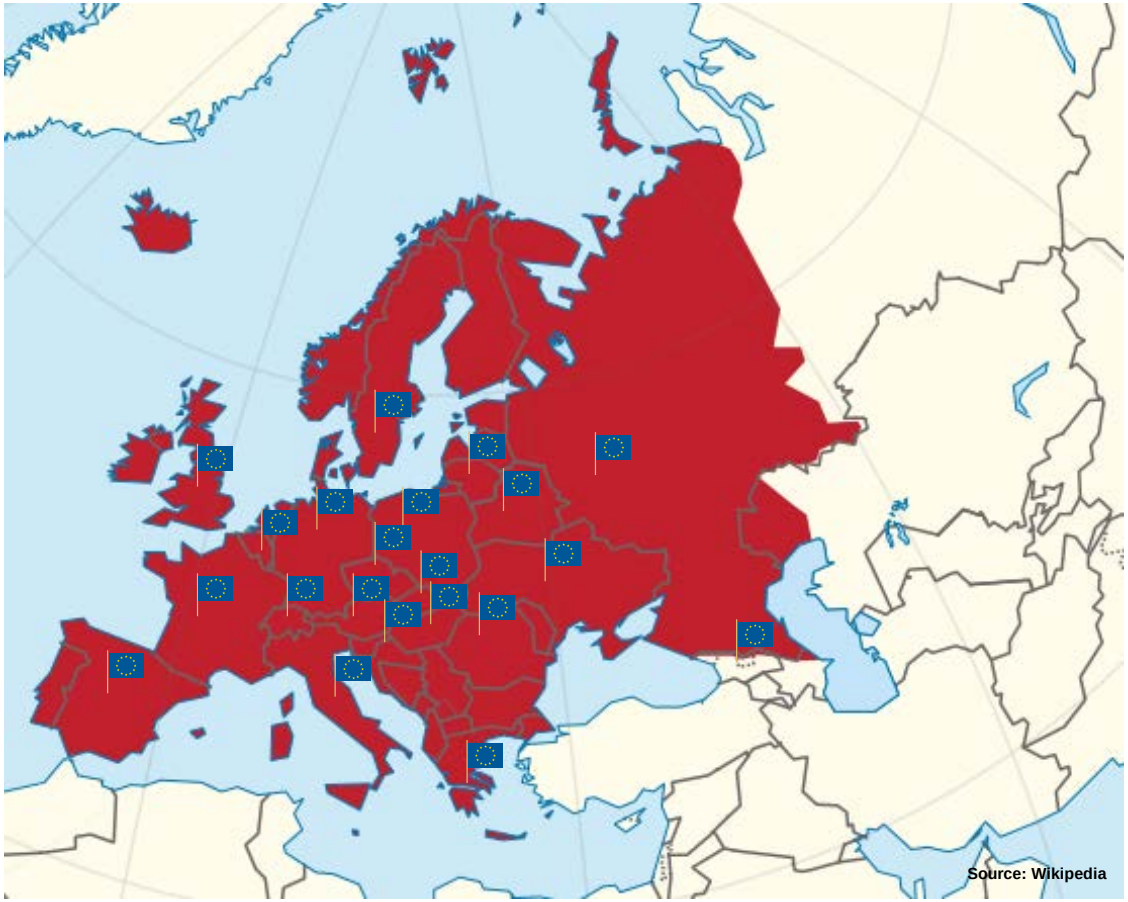
European Studies



- Austria
- Belarus
- Belgium
- Germany
- France
- Georgia
- Greece
- Hungary
- Israel
- Italy
- Lithuania
- Poland
- Romania
- Russia
- Sweden
- Slovakia
- Spain
- Czech Republic
- Ukraine
- United Kingdom

We cover Austria and Germany directly from Munich.
The other countries are covered by local partner CROs.

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Approved Quality

Member of the BVMA and

the EUCROF (European CRO Federation) since 2011

ISO 9001:2008 certified since 2012

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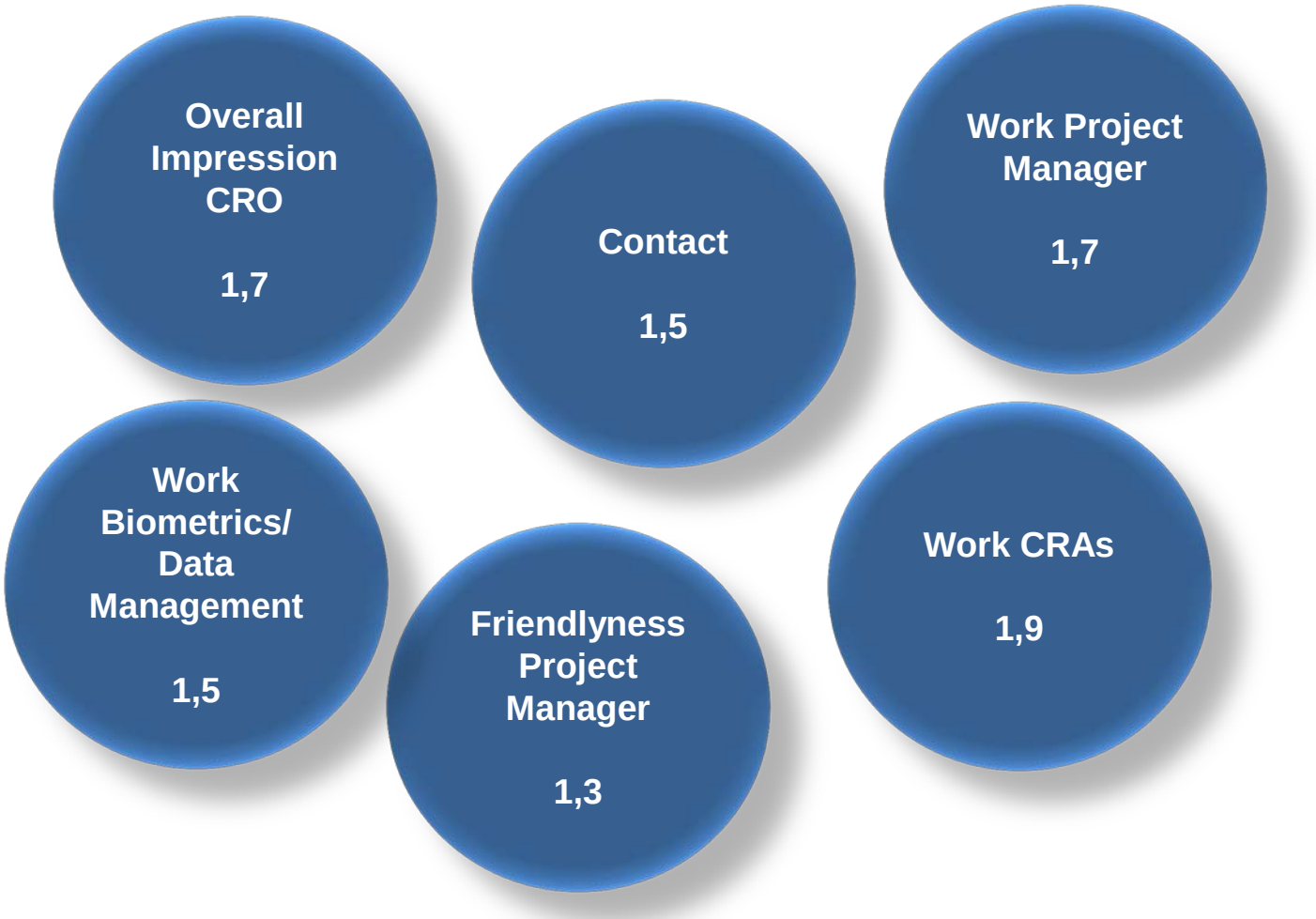
We are recommended by our Customers



1 = “excellent”; 2 = “good”; 3 = “satisfactory”; 4 = “unsatisfactory; 5 = “bad”

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What can we do for you?

Our clients appreciate the close and confident contact with us as well as the transparency form the first offer to the final meeting.

Therefore many clients choose us for the next trial and perform follow-up studies.

We act flexible whether you want to outsource the whole trial or you just need support in defined steps of your project.

Please feel free to contact us and let us

discuss your next project.

Dr. Jens Milde
Head of Clinical Trials

Holger Stammer
CEO

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Contact information

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