



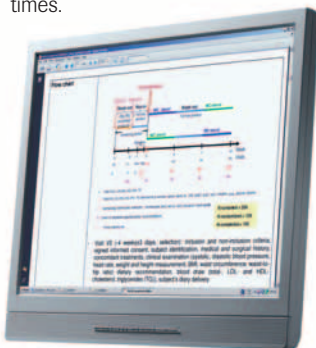
Harrison Clinical Research

Data Management and Statistics

All statistical analysis is done with SAS® software. For special non-parametric tests, Cytel's StatXact software is used.

We are also pleased to work according to your SOPs or templates and all services can be contracted independently. Our aim is to provide you with the best possible service, high-quality documents and rapid turnaround times.

Our primary aims are accuracy, clarity, consistency and quality. We recognise the importance of effective communication in the achievement of your research objectives.



From protocol to final study report – we can manage your clinical trial

Whether you require immediate assistance with a specific task, or professional advice and help with an entire project our commitment to quality and customer service is guaranteed.

Individual and flexible solutions

As each product and each study is unique, the solutions offered are tailored to meet the individual requirements for each project and drug development program

For further information on Harrison Clinical Research Group Services, see also in this series:

- ▶ Central Europe
- ▶ Eastern Europe, Poland, Ukraine, Russia
- ▶ Japan
- ▶ Clinical Pharmacology Unit
- ▶ Clinic for Nutritional Medicine
- ▶ Medical Writing
- ▶ Quality Assurance

The Harrison Clinical Research Group

Harrison Clinical Research Deutschland GmbH

Corporate Office
Albrechtstr. 14
80636 Munich
Germany
Tel. +49 - 89 - 12 66 80-0
Fax +49 - 89 - 12 66 80-24 44

Other Harrison Clinical Research Group Offices

- ▶ Ely, United Kingdom
- ▶ Brussels, Belgium
- ▶ Rehovot, Israel
- ▶ Barcelona, Spain
- ▶ Levallois-Perret, France
- ▶ Milan and Rome, Italy
- ▶ Vienna, Austria
- ▶ Warsaw, Poland
- ▶ Moscow, Russia
- ▶ Kiev, Ukraine
- ▶ Princeton, USA



11010101010111010001001010101010010111010101001100101010111000111010001001010

Harrison

Harrison

CLINICAL RESEARCH - YOUR FULL-TRUST CRO

Harrison Clinical Research is a medically driven independent contract organisation (CRO), founded in 1987.

Harrison Clinical Research offers the full range of services required for the successful development and registration of new pharmaceutical products and medical devices. From single studies to complete development programmes. Clinical trials from Phase I-IIa can be carried out in our own clinics, while Phase II-IV studies can be carried out either locally or globally, as required.

The head office of Harrison Clinical Research is located in Munich, Germany, where our Clinical Pharmacology Unit, the Clinic for Nutritional Medicine, Data Management and Statistics, Medical Writing and Quality Assurance departments are also based.

There are Harrison affiliates in ten European countries, Israel and USA.

All the activities of a Harrison Clinical Research office are performed in strict compliance with the relevant ICH-GCP guidelines. Harrison Clinical Research has been ISO 9001 certified since 1998.

These comprehensive, quality services are performed to the highest international standards.



Statistics

Data Management

1101010101011
1010001001010
1010101001001
1101001100101

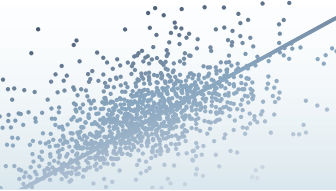


Our **Data Management group** offers more than 15 years experience in a broad range of therapeutic areas and services including:

- ▶ Randomization procedures including central Web-based randomization and stock management
- ▶ CRF design according to HCR or sponsor templates
- ▶ Preparation of Data Management Plans
- ▶ Database (e-CRF) design according to HCR or sponsor SOPs and systems
- ▶ CRF and data query tracking through an electronic database system
- ▶ Data entry and verification
- ▶ Computerized edit checks for missing, implausible or inconsistent data in CRFs
- ▶ Serious Adverse Event Reconciliation
- ▶ Medical coding with coding dictionaries such as MedDRA® or WHO drug dictionary
- ▶ Preparation of CDISC Submission Data Tabulation Modelling (SDTM) /define.xml/ADAM data.

The Data Management group uses the following systems:

- ▶ Marvin from XClinical, a full CDISC-ODM certified CDM system with highly efficient and future-oriented CDISC standardizations. Hybrid system for e-/p-CRF or combinations (e-CRF/p-diary), online access via Internet for all users
- ▶ Partnerships with e-diary vendors (CRF, Invivodata)
- ▶ Sample size calculations using Nquery® software
- ▶ Database transferal to client database, as required, e.g. as SAS datasets, preparation of CDISC submission data model (SDTM) compliant data
- ▶ Standard pharmacokinetic analysis using WinNonlin® or Kinetica™ software
- ▶ Special scanning and OCR software (Cardiff Teleform®) to retrieve data from observational studies, patient diaries or other questionnaires, if applicable.



Error rates for clinical databases are controlled and do not exceed 0.5% (≤ 5 errors per 1000 data fields) as an industry-wide standard. For critical data zero errors based on a 100% review of data are obtainable. This is controlled and documented by database audits against CRFs.

HCR is an associate member of CDISC. CDISC (Clinical data interchange standards consortium, www.cdisc.org) is an open, multi-disciplinary, non-profit organization committed to the development of worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and meta-data for medical and biopharmaceutical product development.

Associate Member of



Our **Biostatistics group** offers:

- ▶ Advice on statistical aspects of study design and sample size issues
- ▶ Statistical analysis plans
- ▶ SAS programming
- ▶ Special programming of non-standard statistical methods
- ▶ Non-compartment pharmacokinetic analysis
- ▶ Production of tables, figures and listings
- ▶ Powerful statistical reports also as an independent service from external databases
- ▶ Participation or Provision of Data in Data Monitoring Committees (DMCs) and Data Safety Monitoring Boards (DSMBs)

