

# Statistics, data management and medical writing services for clinical trials

- Scrupulous procedures and quality control
- Absolute commitment to timelines
- Highly trained staff
- Flexibility to match your needs



Hammersmith  
Medicines Research

[www.hmrlondon.com](http://www.hmrlondon.com)

## Our service to you

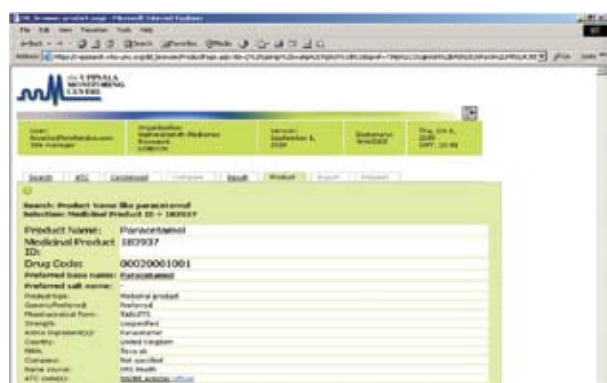
We can provide efficient, high-quality statistics, data management and medical writing services for phase I trials. We've a proven record for meeting the expectations of the world's largest pharmaceutical companies.

## Data management

- CRF design
- trial data management plan
- full review of completed CRF
- database set-up according to CDISC standards
- double-data entry by 2 independent people
- manual and computerised validation checks
- QC report
- coding using MedDRA, WHO DDE, or other dictionaries
- creation of SDTM and AdAM datasets for FDA submission
- export database in SAS or other formats
- laboratory data supplied to sponsor's specification
- validated systems to ensure security of all electronic data

## ClinPlus data management system

- SAS-based, integrated system
- fully 21 CFR Part 11 compliant
- maximum security
- rapid and flexible database setup
- independent double-data entry via customised screens
- multiple logic and consistency checks
- comprehensive query management and data clarification forms
- programmatic data validation
- comprehensive audit trails
- SAS and CDISC import and export
- customised report and listing facilities



## Statistics

- statistical input to trial protocols
- sample size and power calculations
- randomisation codes
- SAS and WinNonlin for statistical and PK analyses
- extensive experience of SAS programming, PK and PD analyses
- statistical analysis plan – ICH compliant
- PK and PD analyses including interim analyses
- multiple comparisons and empirical modelling
- tables, figures, listings using validated SAS programs
- separate PK, PD, and statistical reports



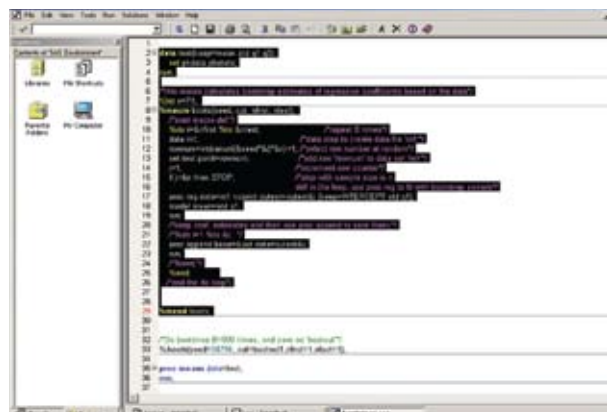
Protocol: XYZ123 Draft Page: 1 of 1  
**Demographic Characteristics Summary**  
 All Treated Subjects

	DRUG A (N=57)	DRUG B (N=65)	DRUG C (N=16)	PLACEBO (N=62)	-Total (N=200)	P-values
<b>Age</b>					200	
MEAN	52.7	54.8	52.4	55.5	54.2	0.365
MEDIAN	55.0	55.0	57.0	58.0	55.5	
MIN MAX	[23 , 68]	[27 , 70]	[26 , 69]	[27 , 70]	[23 , 70]	
STANDARD DEVIATION	9.95	9.64	13.46	8.88	9.85	
<65	50 (88)	53 (82)	13 (81)	54 (87)	170 (85)	
>=65	7 (12)	12 (18)	3 (19)	8 (13)	30 (15)	
<b>Sex (%)</b>					200	
Male	37 (65)	36 (55)	10 (63)	47 (76)	130 (65)	0.118
Female	20 (35)	29 (45)	6 (38)	15 (24)	70 (35)	
<b>Race (%)</b>					200	
ASIAN/NOT PACIFIC	57 (100)	65 (100)	16 (100)	62 (100)	200 (100)	0.276
ISLANDER	1 (2)	1 (2)	0	2 (3)	4 (2)	
BLACK/AFRICAN AMERICAN	4 (7)	12 (18)	1 (6)	8 (13)	25 (13)	
OTHER: EAST INDIAN	0	1 (2)	1 (6)	0	2 (1)	
WHITE	52 (91)	51 (78)	14 (88)	52 (84)	169 (85)	
<b>Ethnicity (%)</b>					200	
HISPANIC/LATINO	5 (9)	7 (11)	2 (13)	1 (2)	15 (8)	0.186
NOT HISPANIC/LATINO	52 (91)	58 (89)	14 (88)	61 (98)	185 (93)	

Program Source: D:\Training\Demog.sas 04DEC08

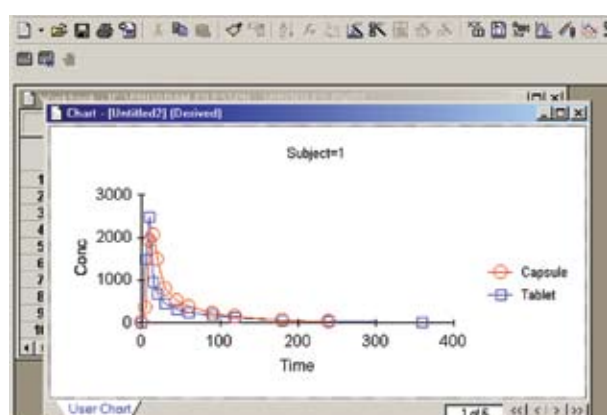
## Computer security

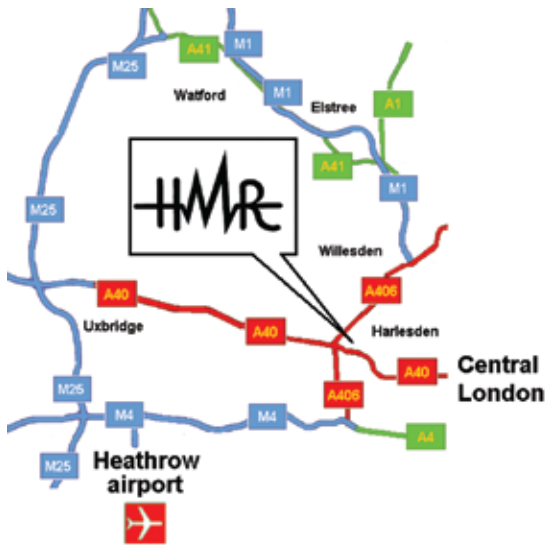
- role-based security system and data access control down to a variable level
- separate system log-on with comprehensive password complexity features
- unique log-in for each employee
- access to data controlled through user privilege settings
- daily back-up of all files



## Timelines

- 2–4 weeks from CRF completion to database lock
- completion of tables, figures, and listings:
  - 2 weeks for simple studies
  - 3 weeks for studies of medium complexity
  - 4 weeks for complex studies





## Medical writing

- design of or advice on CRFs
- clinical trial protocols
- investigator's brochures
- IMP dossiers
- applications to the ethics committee
- applications to the MHRA
- information and consent forms
- interim reports
- pharmacokinetic reports
- pharmacodynamic reports
- statistical reports
- integrated clinical study reports to sponsor's preferred format
- manuscripts or abstracts for publication



Hammersmith Medicines Research Ltd  
Cumberland Avenue  
Park Royal  
London NW10 7EW

[www.hmrlondon.com](http://www.hmrlondon.com)

Phone: 020 8961 4130

Fax: 020 8961 8665

Email: [mboyce@hmrlondon.com](mailto:mboyce@hmrlondon.com)

[swarrington@hmrlondon.com](mailto:swarrington@hmrlondon.com)

[tkumke@hmrlondon.com](mailto:tkumke@hmrlondon.com)

## Quality control

- ISO 9001 accredited
- quality system based on GCP, GMP and Statistical Principles for Clinical Trials
- comprehensive set of SOPs
- corporate member Plain English Campaign