Statistics and data management services for clinical trials

- Established data management and statistical support from experts in clinical trials
- Flexible, efficient, and high quality service
- ICH and CDISC-compliant deliverables

For all enquiries, please contact:

Bhavini Ladwa

Phone: 020 8961 4130
Email: bladwa@hmrlondon.com

Hammersmith Medicines Research

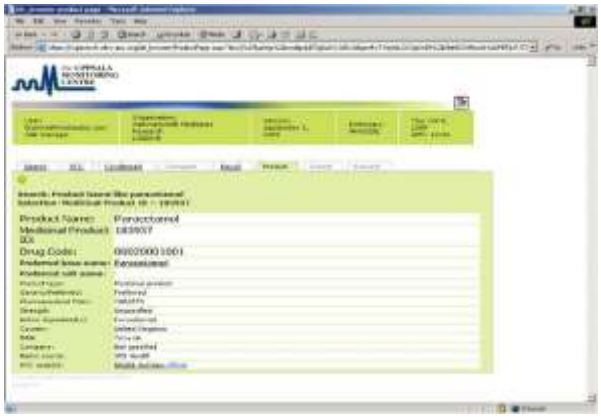
www.hmrlondon.com

First-class clinical trials service

We provide efficient, high quality data management and statistical support for early phase clinical trials. Our experienced data managers, SAS programmers and statisticians have worked closely with our experts in clinical pharmacology on hundreds of clinical trials.

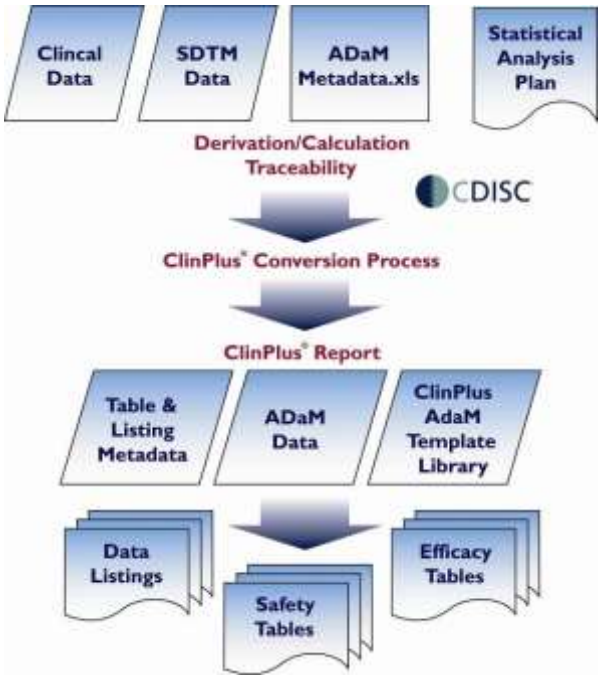
We offer:

- High data quality, integrity and security
- Flexibility:
  - bespoke service, with data accessibility to meet your needs
  - rapid provision of interim data to support dose decisions
  - agile response to protocol amendments
- Seamless flow of data and open communication, to ensure that we meet your timelines
- Full integration with our clinical and medical writing services
- Support for external studies



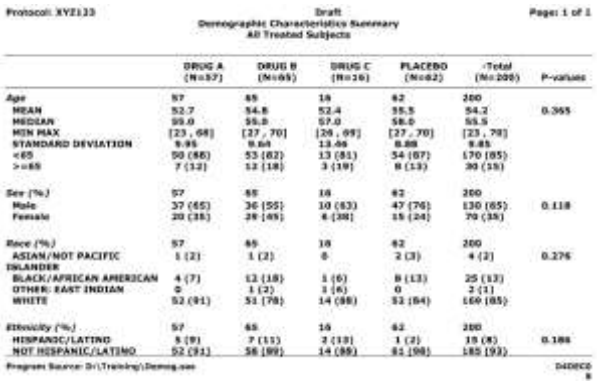
Clinical data management

- Electronic data or paper-based management
- Rapid eCRF /CRF/ design and development, based on CDASH
- CRF annotation based on SDTM
- Database design and build
- Comprehensive database checks – specified, programmed and tested
- Full data processing, including double data entry for paper CRFs
- Query management
- Medical coding
- Reconciliation of safety data
- Transfer and reconciliation of laboratory and external vendor data
- CDISC-compliant deliverables, including SDTM and Define



Clinical statistics

- Protocol input – design, sample size calculations and statistical methods
- Randomisation, including customised, secure emergency unblinding envelopes
- Statistical analysis plan, including output shells
- Interim analysis, including rapid analysis of PK and PD data to support dose decisions
- SAS programs verified by independent programming
- ICH compatible compliant tables, figures and listings
- Statistical review of the clinical study report
- Expert statistical advice

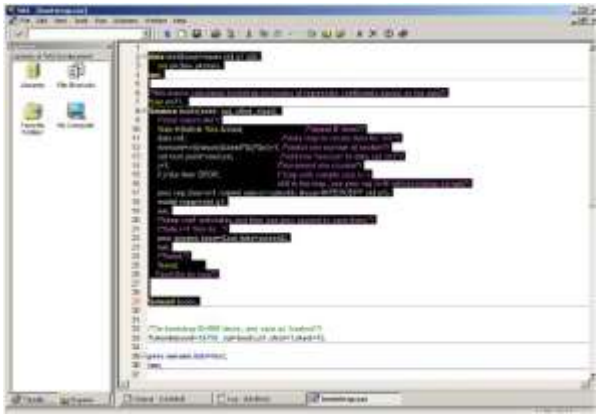


Protocol: XYZ123 — Draft — Page: 1 of 1

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
Age	57	65	16	62	200	
MEAN	52.7	54.8	52.4	55.5	54.2	0.365
MEDIAN	55.0	55.0	57.0	56.0	55.5	
MIN MAX	[23 , 68]	[27 , 70]	[26 , 69]	[27 , 70]	[23 , 70]	
STANDARD DEVIATION	9.95	9.64	13.66	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)	
Sex (%)	57	65	16	62	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)	
Race (%)	57	65	16	62	200	
ASIAN/NOT PACIFIC ISLANDER	1 (2)	1 (2)	0	2 (3)	4 (2)	0.276
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)	
Ethnicity (%)	57	65	16	62	200	
HISPANIC/LATINO	5 (9)	7 (11)	2 (13)	1 (2)	15 (8)	0.188
NOT HISPANIC/LATINO	52 (91)	58 (89)	14 (88)	61 (98)	185 (93)	

Program Source: D:\Training\Demog.sas

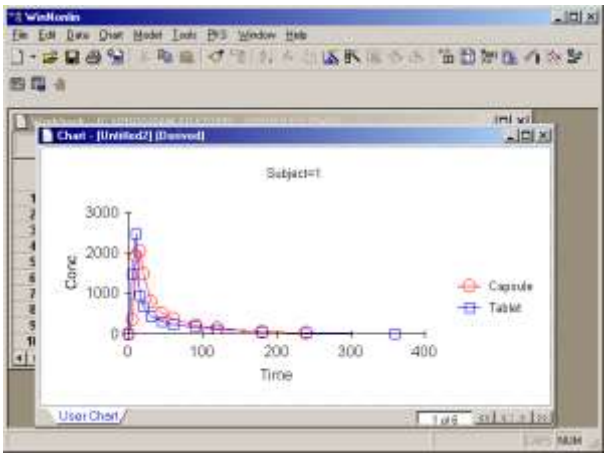


Pharmacokinetics

- Derivation of interim and final parameters
- Statistical analysis of parameters, including accumulation, bioequivalence and dose proportionality

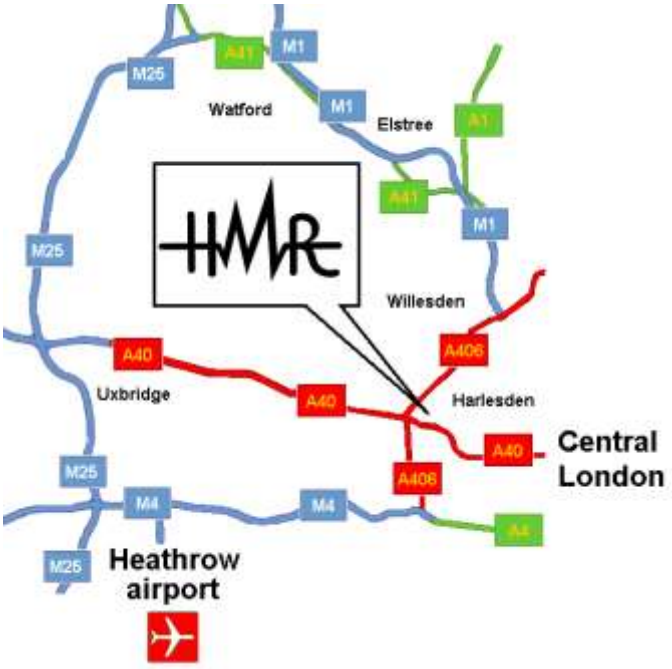
Systems

- We use the following validated, 21 CFR part 11-compliant systems:
  - Medrio
  - ClinPlus
  - SAS
  - WinNonlin



Quality assured

- GCP compliant
- Stringent quality control
- Independent quality assurance
- ISO 9001-certified



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