

Appendix A Glossary

ACP	Acid phosphatase
ACRP	Association of Clinical Research Professionals (http://www.acrpnet.org/)
ACV%	Annualized coefficient of variation
ADR	Adverse drug reaction
AE	Adverse event
ALP	Alkaline phosphatase
ANOVA	Analysis of variance
AP	Antero-posterior
ASIS	Anterior superior iliac spine
BALP	Bone specific alkaline phosphatase
BMC	Bone mineral content in grams
BMD	Bone mineral density in grams per square centimeter. Calculated as the bone mineral content of a bone divided by the area of the bone and as such it is not true density
BMI	Body mass index
BMP	Bone morphogenic proteins
BUA	Broadband ultrasound attenuation measured in decibels per megahertz (dB MHz^{-1}); a measure of the attenuation of ultrasound through the heel
CLIA	Clinical Laboratory Improvement Amendments. An accrediting body for laboratories in the USA (http://www.clianet.org)
CPA	Clinical Pathology Accreditation. An accrediting body for laboratories in the UK (http://www.cpa-uk.demon.co.uk/index.htm)
CPMP	The Committee for Proprietary Medicinal Products. The European Committee responsible for reviewing standards for Good Clinical Practice
CRA	Clinical research associate. A representative of a CRO responsible for liaison between the CRO and sites participating in the trial
CRO	Clinical research organization. A company responsible for administering the trial on behalf of a sponsor
CT	Computed tomography
CTA	Clinical Trial Agreement on Study Consent
CTx	C-terminal telopeptide or crosslaps
CUSUM	Cumulative sum charts
CV	Curriculum vitae
CV, CV%	Coefficient of variation
DPyd	Deoxypridinoline

DSMC	Data Safety Monitoring Committee
DXA	Dual energy X-ray absorptiometry. The principal technique used for measuring BMD
ED	Effective dose measured in millisieverts (mSv). A measure of radiation dose that can be related directly to the risk of the radiation exposure
ELISA	Enzyme linked immunosorbent assay
EQA	External quality assurance
ESD	Entrance skin dose measured in milligrays (mGy)
ESP	European Spine Phantom
FDA	Food and Drug Administration. The US agency responsible for the licensing of pharmaceuticals. A good source of guidelines on the conduct of clinical trials is their website http://www.fda.gov/
GCP	Good Clinical Practice. The international standard for conduct of clinical trials
GHyL	Galactosyl hydroxylysine
GLP	Good Laboratory Practice
GP	General practitioner or primary care physician
GREES	The Group for the Respect of Ethics and Excellence in Science
HPLC	High performance liquid chromatography
HRT	Hormone replacement therapy or estrogen replacement therapy
ICH	International Committee on Harmonization. Produces international standards for the conduct of clinical trials (http://www.ifpma.org/ich1.html)
ICP-MS	Inductively coupled plasma mass spectrometry
ICR	Institute of Clinical Research (http://www/instituteofclinicalresearch.org/)
ICTP	Type I collagen C-terminal telopeptide
IDSC	International DXA Standardization Committee
IND	Investigational new drug
IQC	Internal quality control
IRB/IEC	Institutional Review Board or Independent Ethics Committee responsible for reviewing and approving the ethical basis of the trial at each participating center
IRMA	Immunoradiometric assay
ISCD	International Society for Clinical Densitometry (http://www.iscd.org/)
ISO	International Standards Organization (http://www.iso.ch/iso/en/ISOOnline.openerspage)
MREC	Multi-Centre Research Ethics Committee. Independent Ethics Committees set up to review multi-center research in the UK (http://www.corec.org.uk/)
MRI	Magnetic resonance imaging
MXA	Morphometric X-ray analysis. A technique from radiographers for lateral scans of the spine using DXA that measures the height of vertebra, allowing the identification of vertebral fractures
NEQAS	UK National External Quality Assessment Schemes (http://www.ukneqas.org.uk/)
NHANES	The National Health and Nutrition Examination Survey; a survey conducted by the National Center for Health Statistics, part of the Centers for Disease Control and Prevention, US Public Health Service.

This survey has been designed to collect information about the health and diet of people in the United States. NHANES is unique in that it combines a home interview with health tests. The tests included measuring BMD at the femur (<http://www.cdc.gov/nchs/nhanes.htm>)

NIBSC	National Institute for Biological Standards and Control (http://www/nibsc.ac.uk)
NIH	National Institutes of Health. An American agency who commission and fund health research. They have produced consensus guidelines on osteoporosis (http://www.nih.gov/)
NIST	National Institute of Standards and Technology (http://www.nist.gov/)
NME	New molecular entity. A new drug under development being tested in a clinical trial
NNT	Numbers needed to treat (to prevent one fracture)
NOF	National Osteoporosis Foundation (USA) (http://www.nof.org/)
NOS	National Osteoporosis Society (UK) (http://www.nos.org.uk/)
NTx	N-terminal telopeptide linked crosslink
OA	Osteoarthritis
OHP	Hydroxyproline
PA	Postero-anterior
PDXA	Peripheral DXA measures BMD of forearm or heel
PQCT	Peripheral QCT – usually measures BMD of the forearm
PTH	Parathyroid hormone
Pyd	Pyridinoline
QA	Quality assurance – review of the quality control information by sampling or audit
QC	Quality control. The ongoing sampling of a process to ensure that the quality of the process is within defined limits. For example, daily phantom measurements on DXA equipment
QCT	Quantitative computed tomography. A method of measuring bone density from a CT scan
QUALEFFO	Quality of Life Questionnaire of the European Foundation of Osteoporosis
QUS	Quantitative ultrasound. A technique that measures the attenuation of ultrasound (BUA) through the heel and the velocity or speed of sound (VOS or SOS). These measures are often combined to calculate the stiffness or Stiffness Index
RCT	Randomized controlled trial
RIA	Radioimmunoassay
RIQAS	Randox International Quality Assessment Scheme (http://www.randox.com/riqas.htm)
RMS SD	Root mean squared standard deviation
ROC	Receiver operating characteristics
ROI	Region of interest. Area set on image to calculate BMD
SADR	Serious adverse drug reaction
SAE	Serious adverse event
sBMD	Standardized BMD in milligrams per square centimeter
SCV%	Standardized coefficient of variation
SD	Standard deviation
SEE	Standard error of estimate
SERM	Selective estrogen receptor modulator

SF-36	A validated health status questionnaire
SMO	Site management organization. A local research organization or hospital that recruits subjects and carries out the clinical trial on behalf of a CRO
SOCRA	Society of Clinical Research Associates (http://www.socra.org/)
SOP	Standard operating procedure
SOS	Speed of sound ($\text{m}\cdot\text{s}^{-1}$) measured using QUS in the heel
SSC	Study site coordinator
SSE	Residual sum of squares
TALP	Total alkaline phosphatase
tns gene	Tissue non-specific gene
TRACP	Tartrate resistant acid phosphatase
VOS	Velocity of sound ($\text{m}\ \text{s}^{-1}$) measured using QUS in the heel
WEQAS	Wales External Assessment Scheme
WHO	World Health Organization (http://www.who.int/)

Appendix B **Sample Data from the Example Study Used in this Book**

See table that begins overleaf.

The BMD measurements are the AP spine BMD in $g\ cm^{-2}$. The BUA is in $dB\ MHz^{-1}$. There are missing value in the BUA data because of equipment failure. Group 2 is the treatment group and Group 1 the placebo. There is additional demographic information such as age, center and smoking habits. Smoking is coded as 1 = non-smoker, 2 = smoker.

Age	Baseline BMD	BMD 1 year	BMD 2 years	BMD 3 years	BMD 4 years	Baseline BUA	BUA 1 year	BUA 2 years	BUA 3 years	BUA 4 years	Group	Center	Smoking
50	1.246	1.285	1.285	1.325	1.325	1.325					2	1	2
48	0.98	0.966	1.01	1.033	1.015						2	2	2
48	1.068	1.081	1.052	1.076	1.09	115	114	110	108	104	2	1	2
49	0.956	0.964	0.973	0.988	1.013	119	118	117	118	119	2	2	1
52	1.001	1.019	1.051	1.087	1.093	99.1	95	96	98	99	2	1	2
57	0.844	0.866	0.886	0.909	0.912	111.5	107	114	115	112	2	2	2
50	0.825	0.927	0.908	0.948	0.979	118.7	124	122	125	130	2	1	2
51	1.108	1.129	1.128	1.14	1.125	140.5	137	141	140	139	2	2	1
45	1.053	1.069	1.042	1.12	1.098	106.9	107	108	107	106	2	1	1
57	0.861	0.895	0.929	0.977	0.936	110.9	110	108	107	108	2	2	2
51	1.018	1.026	1.038	1.041	1.053	116.5	129	120	116	118	2	1	2
58	0.883	0.904	0.912	0.961	0.972	134	128	124	120	121	2	2	1
51	0.961	0.96	0.991	1.022	1.022	105.2	101	122	123	118	2	1	2
50	0.911	0.983	1.013	1.018	1.015	120.5	121	122	123	120	2	2	2
53	0.911	0.926	0.938	0.942	0.944	132	137	130	125	120	2	1	1
52	0.952	1.02	0.97	1.053	1.031	114	111	113	111	110	2	2	2
52	1.068	1.078	1.134	1.142	1.148	120	120	120	121	118	2	1	2
52	0.856	0.875	0.89	0.912	0.902	104.4	103	102	101	99	2	2	1
51	0.808	0.82	0.793	0.8	0.811	145	125	125	127	129	2	1	2
56	0.927	0.965	0.968	0.985	1.017	125	121	114	110	110	2	2	1
53	1.185	1.235	1.235	1.297	1.338	112.3	112	110	108	111.2	2	1	1
54	1.005	1.062	1.056	1.096	1.084	125	125	124	123	122	2	2	1
56	0.73	0.817	0.819	0.819	0.823	111.1	117	114	113	112	2	1	1
49	0.789	0.814	0.814	0.839	0.839	101	99	109	105	113	2	2	1
50	1.019	1.059	1.068	1.11	1.105	110	107	109	105	113	2	1	2
48	0.974	0.986	0.969	1.006	1.016	114	112	114	114	112	2	2	1
47	0.778	1.028	0.979	1.031	1.021	119	114	116	118	118	2	1	2
59	0.778	0.836	0.844	0.853	0.874	106.5	106	105	105	106	2	2	1
58	0.887	0.95	0.951	0.973	0.959	105.6	110	113	110	115	2	1	1
49	0.854	0.917	0.946	0.916	0.943	103.2	106	106	99	103	2	2	2

The BMD measurements are the AP spine BMD in $g\ cm^{-2}$. The BUA is in $dB\ MHz^{-1}$. There are missing value in the BUA data because of equipment failure. Group 2 is the treatment group and Group 1 the placebo. There is additional demographic information such as age, center and smoking habits. Smoking is coded as 1 = non-smoker, 2 = smoker. (continued)

Age	Baseline BMD	BMD 1 year	BMD 2 years	BMD 3 years	BMD 4 years	Baseline BUA	BUA 1 year	BUA 2 years	BUA 3 years	BUA 4 years	Group	Center	Smoking
56	0.735	0.737	0.711	0.68	0.689	99.7	95	96	92	91.6	1	1	1
50	0.789	0.728	0.697	0.685	0.685	120	113	115	114	101	1	2	2
55	0.797	0.783	0.774	0.767	0.762	107	105	89	94	101	1	1	2
50	0.803	0.793	0.764	0.758	0.758	109.8	104	96	101	106	1	2	2
45	0.822	0.781	0.823	0.84	0.813	110.8	109	101	101	103	1	1	2
48	0.829	0.833	0.839	0.839	0.809	108	105	100	101	90	1	2	1
53	0.83	0.825	0.81	0.773	0.854	115	110	112	106	109	1	1	1
51	0.861	0.861	0.835	0.858	0.876	113.2	113	110	107	91	1	2	2
54	0.884	0.856	0.836	0.845	0.826	107	106	101	100	109	1	1	1
53	0.905	0.921	0.922	0.955	0.931	109	108	104	102	101	1	2	2
50	0.907	0.864	0.877	0.867	0.888	140	135	106	101	101	1	1	1
57	0.935	0.923	0.912	0.911	0.908	112	109	114	112	110	1	2	1
53	0.913	0.898	0.895	0.887	0.924	106.8	105	101	90	103	1	1	2
50	0.926	0.941	0.876	0.861	0.855	111.1	109	113	110	111	1	2	1
52	0.943	0.912	0.897	0.941	0.945	110.8	113	109	112	116	1	1	2
55	0.967	0.933	0.94	0.943	0.927						1	2	2
58	0.976	0.95	0.965	0.963	0.955	109.9	105	106	105	99	1	1	1
49	0.975	0.969	0.969	0.973	1.013	135	132	129	131	123	1	2	2
55	0.952	0.94	0.926	0.938	0.917	103.4	97	100	97	89.9	1	1	1
47	0.988	0.966	0.895	0.901	0.889	110	107	104	97	103	1	2	1
50	0.996	0.93	0.921	0.918	0.936	124.8	109	119	115	114.9	1	1	2
51	1.004	1.017	0.969	1.002	0.969	120.5	123	118	115	117	1	2	1
47	1.01	0.972	0.948	0.923	0.886	110.1	109	110	109	104	1	1	2
48	1.036	1.036	1	1.016	0.974	114.3	111	109	100	108	1	2	2
53	1.056	1.109	1.042	1.071	1.06	110	102	104	103	108	1	1	1
49	1.06	1.025	0.982	0.97	0.927	106	105	97	93	98	1	2	1
49	1.068	1.017	0.978	1.022	1.002	119	116	121	115	111	1	1	1
54	1.08	1.069	1.07	1.085	1.099	125.8	126	118	104	123	1	2	1
52	1.116	1.073	1.051	1.045	1.091	120	114	114	104	123	1	1	2
54	1.163	1.169	1.141	1.102	1.102						1	2	2

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