CTRG WEBSITE GLOSSARY

AE	Adverse event
AR	Adverse reaction
ARSAC	Administration of Radioactive Substances Advisory Committee
BRC	Biomedical Research Centre
CA	Competent Authority
CE	Conformité Européenne
CI	Chief Investigator
CRA	Clinical Research Associate (Monitor)
CRF	Case Report Form
CRO	Contract Research Organisation
CSP	Co-ordinated System for NHS Permissions
CT	Clinical Trials
CTA	Clinical Trials Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTRG	Clinical Trials and Research Governance
CUREC	Central University Research Ethics Committee
CV	Curriculum Vitae
DMC/DMSC	Data Monitoring Committee / Data Monitoring and Safety Committee
DOH	Department of Health
DPA	Data Protection Act
DSUR	Development Safety Update Report
EUCTD	European Union Clinical Trials Directive
EUDRACT	European Union Drug Regulating Authorities Clinical Trials
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GP	General Practitioner
HRA	Health Research Authority
HTA	Human Tissue Act/Authority
IB	Investigators Brochure

ICF	Informed Consent Form
ICH	International Conference of Harmonisation
ICMJE	International Committee of Medical Journal Editors
IEC	Independent Ethics Committee
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
IRB	Independent Review Board
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number Register
MCA	Mental Capacity Act
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
OUHT	Oxford University Hospitals NHS Trust
OXTREC	Oxford Tropical Research Ethics Committee
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
PIS	Participant/ Patient Information Sheet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RGF	Research Governance Framework
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SmPC	Summary of Medicinal Product Characteristics
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reactions
TMF	Trial Master File
TSG	Oxford University Hospitals Trust / University of Oxford Trials Safety Group
TVCLRN	Thames Valley Comprehensive Local Research Network