Common Acronyms – Australian Therapeutics Industry

ACB	TGA Advisory Committee on Biologicals
ACCM	TGA Advisory Committee on Complementary Medicines
ACM	TGA Advisory Committee on Medicines
ACMD	TGA Advisory Committee on Medical Devices
ACMS	TGA Advisory Committee on Medicines Scheduling
ACPM	TGA Advisory Committee on Prescription Medicines
ACSOM	TGA Advisory Committee on the Safety of Medicines
ACSS	Australia-Canada-Singapore-Switzerland Regulators Consortium
ACTA	Australian Clinical Trials Alliance
ACV	TGA Advisory Committee on Vaccines
ADR	Adverse Drug Reaction
AE	Adverse Event
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers' Advisory Council
ANZCTR	Australian New Zealand Clinical Trials Registry
API	Active Pharmaceutical Ingredient
ARGATG	Australian Regulatory Guidelines for Advertising Therapeutic Goods
ARGCM	Australian Regulatory Guidelines for Complementary Medicines
ARGMD	Australian Regulatory Guidelines for Medical Devices
ARGOM	Australian Regulatory Guidelines for OTC Medicines
ARGPM	Australian Regulatory Guidelines for Prescription Medicines
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARTG	Australian Register of Therapeutic Goods
CAPA	Corrective and Preventative Action
CDISC	Clinical Data Interchange Standards Consortium
CHF	Consumers Health Forum of Australia
CIOMS	Council for International Organizations of Medical Sciences
CM	Complementary Medicines Australia
CMI	Consumer Medicine Information
CRO	Contract/Clinical Research Organisation
CRF	Case report form (data collection form in clinical trials)
CSR	Clinical Study Report
CTCF	Clinical Trials Collaborative Forum
CTN	Clinical Trials Network
CTN / CTX	Clinical trial notification / Clinical trial exemption scheme
CTPRF	Clinical Trials Project Reference Group
DMF	Drug master file
DSMB	Data Safety Monitoring Board (or IDMC)
eBS	TGA eBusiness Services
eCTD	electronic Common Technical Document
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
GCDMP	Good Clinical Data Management Practice
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMO	Genetically-Modified Organism
GMP	Good Manufacturing Practice
GTRAP	TGA Gene and Related Therapies Research Advisory Panel
HBV/HCV	Hepatitis B / Hepatitis C virus
HCP	Health Care Provider
HCT	Human cellular and tissue therapies
HPCs	Haematopoietic progenitor cells
HREC	Human Research Ethics Committee
HTA	Health Technology Assessment
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IDMC	Independent Data Monitoring Committee
IDMP	Identification of Medicinal Products
IIR	Investigator-Initiated Research
IIT	Investigator-Initiated Trials

Common Acronyms – Australian Therapeutics Industry

IoT	Internet of Things
IMDRF	International Medical Device Regulators Forum
IRB	Institutional Review Board (US)
ISO	International standard
IVD or IVDD	In vitro diagnostic device
KPI	Key Performance Indicator
MA	Medicines Australia, also Medical Affairs
MoI/MoU	Memorandum of Intent / Memorandum of Understanding
MMDR	Medicines and Medical Devices Regulation
MRA	Mutual Recognition Agreement
MRFF	Medical Research Future Fund
MSAC	Medical Services Advisory Committee
MTAA	Medical Technology Association of Australia
NBE	New Biological Entity
NCCTG	National Coordinating Committee on Therapeutic Goods
NCE	New chemical entity
NCTGF	National Clinical Trials Governance Framework
NHMRC	National Health and Medical Research Council
NIH	US National Institutes of Health
NMP	National Medicines Policy
NMA	National Mutual Acceptance
OGTR	Office of Gene Technology Regulator
OTC	Over-the-Counter (medicines)
PAR	Provisional ARTG record
PBAC	Pharmaceutical Benefits Advisory Committee
PI	Principal Investigator OR Product Information
PIC/PICF	Participant Informed Consent (Form)
PIC/S	Pharmaceutical Inspection Convention / Pharmaceutical Inspection Co-operation Scheme
PLAC	Prostheses List Advisory Committee
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PQS	Pharmaceutical Quality System - updated terminology for QMS
PV	Pharmacovigilance (Safety)
QA	Quality Assurance
QbD	Quality by Design
QC	Quality Control
QMS	Quality Management System
QRM	Quality Risk Management
QUM	Quality Use of Medicines
RBM	Risk-based Monitoring
RCT	Randomised Controlled Trial
REGIS	NSW Research Ethics and Governance Information System
RDTF	Research & Development Task Force
RMP	Risk Management Plan
RWD / RWE	Real world data / Real world evidence
SAE	Serious Adverse Event
SaMD	Software as a Medical Device
SAS	Special Access Scheme
SIP	The TransCelerate Shared Investigator Platform
SMF	Site Master File
SOP	Standard Operating Procedure
SPC / SmPC	Summary of product characteristics
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (“Poisons Standard)
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TGACC	Therapeutic Goods Advertising Code Council
TGC	Therapeutic Goods Committee
TGO	Therapeutic goods order
TICC	TGA-Industry Consultative Committee
TMF	Trial Master file (eTMF = electronic trial master file)
TWG	Technical Working Groups [manufacturing]
UDI	Unique Device Identification
WHO	World Health Organisation