

ETCTN CTCAE v4.03 to CTCAE v5 CTEP-AERS User Guide

Beginning in December 2017, ETCTN study builds began with the CTEP-AERS integration for SAE reporting included in the base structure. This means that most ETCTN studies activated in early 2018 include this important integration. All such studies will be migrated from CTCAE v4.03 to CTCAE v5.0 between April and July 2018. During that time, for those studies only, CTEP-AERS will automatically convert v4.03 codes to v5.0. Data entry in Rave should continue with the v4.03 codes until sites are notified that the migration has been scheduled and completed.

During the conversion period **and beyond**, older ETCTN studies will continue to use CTCAE v4.03 codes in Rave EDC, but must be mapped to the v5.0 codes for any other applications. Some mapping is automatic, but not all. This user guide is relevant for the manual mapping that is required.

Since CTEP is converting to CTCAE v5.0 as of 1-Apr-2018, for all studies that contain v4.03 codes, CTMS will automatically:

- Map legacy data from v4.03 to v5.0 for CDUS submissions
- Map legacy data to CTCAE v5.0 in our Web Reporting application.

Legacy ETCTN studies which do not contain the CTEP-AERS integration will continue to require manual entry of Adverse Event and Serious Adverse Event data into CTEP-AERS. The vast majority of the v4.03 codes correspond directly without change to CTCAE v5.0. For the small subset of codes that have changed, ETCTN sites should use the below table when manually entering data into CTEP-AERS. This will facilitate accurate mapping of Rave data into the CTEP Adverse Event Reporting System.

The below table is sorted alphabetically by the v4.03 CTCAE term. Note that some grades change between v4.03 and v5.0.

In Rave

In CTEP-AERS

v4.03 CTCAE Term	Grade	Mapped to→	v5.0 CTCAE Term	Grade	Other Specify
Acute coronary syndrome	2	Mapped to→	Chest pain - cardiac	2	N/A
Acute coronary syndrome	3	Mapped to→	Chest pain - cardiac	3	N/A
Acute coronary syndrome	4	Mapped to→	Myocardial infarction	4	N/A
Acute coronary syndrome	5	Mapped to→	Myocardial infarction	5	N/A
Acute kidney injury	1	Mapped to→	Creatinine increased	2	N/A
Acute kidney injury	2	Mapped to→	Creatinine increased	2	N/A
Agitation	5	Mapped to→	Psychiatric disorders - Other, specify	5	Agitation
Anal mucositis	4	Mapped to→	Anal ulcer	4	N/A
Anal mucositis	5	Mapped to→	Anal ulcer	5	N/A
Anxiety	5	Mapped to→	Psychiatric disorders - Other, specify	5	Anxiety
Appendicitis perforated	2	Mapped to→	Infections and infestations - Other, specify	2	Appendicitis perforated
Azoospermia	3	Mapped to→	Azoospermia	2	N/A
Confusion	5	Mapped to→	Psychiatric disorders - Other, specify	5	Confusion
Conjunctivitis infective	5	Mapped to→	Infections and infestations - Other, specify	5	Conjunctivitis infective
Constrictive pericarditis	3	Mapped to→	Pericarditis	3	N/A
Constrictive pericarditis	4	Mapped to→	Pericarditis	4	N/A
Constrictive pericarditis	5	Mapped to→	Pericarditis	5	N/A
Corneal ulcer	2	Mapped to→	Corneal ulcer	3	N/A
Death neonatal	5	Mapped to→	Death neonatal	4	N/A
External ear inflammation	1	Mapped to→	Otitis externa	1	N/A
External ear inflammation	2	Mapped to→	Otitis externa	2	N/A
External ear inflammation	3	Mapped to→	Otitis externa	3	N/A
External ear inflammation	4	Mapped to→	Otitis externa	4	N/A
External ear inflammation	5	Mapped to→	Otitis externa	5	N/A
Fallopian tube perforation	1	Mapped to→	Injury, poisoning and procedural complications - Other, specify	1	Fallopian tube perforation

In Rave

In CTEP-AERS

v4.03 CTCAE Term	Grade	Mapped to→	v5.0 CTCAE Term	Grade	Other Specify
Fallopian tube stenosis	1	Mapped to→	Reproductive system and breast disorders - Other, specify	1	Fallopian tube stenosis
Fallopian tube stenosis	2	Mapped to→	Reproductive system and breast disorders - Other, specify	2	Fallopian tube stenosis
Fallopian tube stenosis	3	Mapped to→	Reproductive system and breast disorders - Other, specify	3	Fallopian tube stenosis
Fallopian tube stenosis	4	Mapped to→	Reproductive system and breast disorders - Other, specify	4	Fallopian tube stenosis
Fallopian tube stenosis	5	Mapped to→	Reproductive system and breast disorders - Other, specify	5	Fallopian tube stenosis
Female genital tract fistula	1	Mapped to→	Reproductive system and breast disorders - Other, specify	1	Female genital tract fistula
Female genital tract fistula	2	Mapped to→	Reproductive system and breast disorders - Other, specify	2	Female genital tract fistula
Female genital tract fistula	3	Mapped to→	Reproductive system and breast disorders - Other, specify	3	Female genital tract fistula
Female genital tract fistula	4	Mapped to→	Reproductive system and breast disorders - Other, specify	4	Female genital tract fistula
Female genital tract fistula	5	Mapped to→	Reproductive system and breast disorders - Other, specify	5	Female genital tract fistula
Fetal death	5	Mapped to→	Pregnancy loss	4	N/A
Hemolytic uremic syndrome	1	Mapped to→	Hemolysis	1	N/A
Intraoperative skin injury	1	Mapped to→	Injury, poisoning and procedural complications - Other, specify	1	Intraoperative skin injury
Intraoperative skin injury	2	Mapped to→	Injury, poisoning and procedural complications - Other, specify	2	Intraoperative skin injury

In Rave

In CTEP-AERS

v4.03 CTCAE Term	Grade	Mapped to→	v5.0 CTCAE Term	Grade	Other Specify
Intraoperative skin injury	3	Mapped to→	Injury, poisoning and procedural complications - Other, specify	3	Intraoperative skin injury
Intraoperative skin injury	4	Mapped to→	Injury, poisoning and procedural complications - Other, specify	4	Intraoperative skin injury
Intraoperative skin injury	5	Mapped to→	Injury, poisoning and procedural complications - Other, specify	5	Intraoperative skin injury
Irregular menstruation	3	Mapped to→	Amenorrhea	2	N/A
IVth nerve disorder	1	Mapped to→	Trochlear nerve disorder	1	N/A
IVth nerve disorder	2	Mapped to→	Trochlear nerve disorder	2	N/A
IVth nerve disorder	3	Mapped to→	Trochlear nerve disorder	3	N/A
Libido increased	2	Mapped to→	Libido increased	1	N/A
Libido increased	3	Mapped to→	Libido increased	1	N/A
Menopause	1	Mapped to→	Premature menopause	2	N/A
Menopause	2	Mapped to→	Premature menopause	2	N/A
Menopause	3	Mapped to→	Premature menopause	2	N/A
Myocarditis	1	Mapped to→	Cardiac disorders - Other, specify	1	Myocarditis
Oligospermia	2	Mapped to→	Oligospermia	1	N/A
Oligospermia	3	Mapped to→	Oligospermia	1	N/A
Otitis externa	2	Mapped to→	Otitis externa	1	N/A
Ovulation pain	1	Mapped to→	Ovulation pain	2	N/A
Ovulation pain	3	Mapped to→	Ovulation pain	2	N/A
Pelvic floor muscle weakness	4	Mapped to→	Reproductive system and breast disorders - Other, specify	4	Pelvic floor muscle weakness
Pelvic floor muscle weakness	5	Mapped to→	Reproductive system and breast disorders - Other, specify	5	Pelvic floor muscle weakness
Penile infection	2	Mapped to→	Penile infection	1	N/A

<h1>In Rave</h1>		<h1>In CTEP-AERS</h1>
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v4.03 CTCAE Term	Grade	Mapped to→	v5.0 CTCAE Term	Grade	Other Specify
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Peripheral sensory neuropathy	5	Mapped to→	Nervous system disorders - Other, specify	5	Peripheral sensory neuropathy
Personality change	5	Mapped to→	Psychiatric disorders - Other, specify	5	Personality change
Phlebitis infective	2	Mapped to→	Phlebitis infective	1	N/A
Premature menopause	3	Mapped to→	Premature menopause	2	N/A
Retinal detachment	1	Mapped to→	Retinal detachment	3	N/A
Retinal detachment	2	Mapped to→	Retinal detachment	3	N/A
Retinal tear	3	Mapped to→	Retinal detachment	3	N/A
Retinal tear	4	Mapped to→	Retinal detachment	4	N/A
Reversible posterior leukoencephalopathy syndrome	1	Mapped to→	Nervous system disorders - Other, specify	1	Reversible posterior leukoencephalopathy syndrome
Scrotal infection	2	Mapped to→	Scrotal infection	1	N/A
Spleen disorder	1	Mapped to→	Blood and lymphatic system disorders - Other, specify	1	Spleen disorder
Spleen disorder	2	Mapped to→	Blood and lymphatic system disorders - Other, specify	2	Spleen disorder
Spleen disorder	4	Mapped to→	Blood and lymphatic system disorders - Other, specify	4	Spleen disorder
Spleen disorder	5	Mapped to→	Blood and lymphatic system disorders - Other, specify	5	Spleen disorder
Testicular disorder	5	Mapped to→	Reproductive system and breast disorders - Other, specify	5	Testicular disorder
Thrombotic thrombocytopenic purpura	1	Mapped to→	Hemolysis	1	N/A
Unintended pregnancy	3	Mapped to→	Pregnancy, puerperium and perinatal conditions - Other, specify	3	Unintended pregnancy

In Rave			In CTEP-AERS		
v4.03 CTCAE Term	Grade	Mapped to→	v5.0 CTCAE Term	Grade	Other Specify
Uterine perforation	1	Mapped to→	Injury, poisoning and procedural complications - Other, specify	1	Uterine perforation
Vaginal infection	2	Mapped to→	Vaginal infection	1	N/A
Vaginal inflammation	5	Mapped to→	Reproductive system and breast disorders - Other, specify	5	Vaginal inflammation
Vaginal perforation	1	Mapped to→	Reproductive system and breast disorders - Other, specify	1	Vaginal perforation
Vaginismus	1	Mapped to→	Reproductive system and breast disorders - Other, specify	1	Vaginismus
Vaginismus	2	Mapped to→	Reproductive system and breast disorders - Other, specify	2	Vaginismus
Vaginismus	3	Mapped to→	Reproductive system and breast disorders - Other, specify	3	Vaginismus
Wolff-Parkinson-White syndrome	1	Mapped to→	Cardiac disorders - Other, specify	1	Wolff-Parkinson-White syndrome
Wolff-Parkinson-White syndrome	2	Mapped to→	Cardiac disorders - Other, specify	2	Wolff-Parkinson-White syndrome
Wolff-Parkinson-White syndrome	3	Mapped to→	Cardiac disorders - Other, specify	3	Wolff-Parkinson-White syndrome
Wolff-Parkinson-White syndrome	4	Mapped to→	Cardiac disorders - Other, specify	4	Wolff-Parkinson-White syndrome
Wolff-Parkinson-White syndrome	5	Mapped to→	Cardiac disorders - Other, specify	5	Wolff-Parkinson-White syndrome
Wound infection	2	Mapped to→	Wound infection	1	N/A