

DOMAIN	SOTM域描述	SOTM Domain Description	SOTM域结构	SOTM Domain Structure	Key Variables	通用观测类别
AE	Adverse Events	不良事件	每个受试者每次不良事件一条记录	One record per adverse event per subject	STUDYID,USUBJID, AEDECOD,AESTDTC	事件类
CE	Clinical Events	临床事件	每个受试者每次临床事件一条记录	One record per event per subject	STUDYID,USUBJID, CETERM, CESTDTC	事件类
CM	Concomitant/Prior Medications	既往与合并用药	每个受试者每次给药或每个用法一条记录	One record per recorded intervention occurrence or constant-dosing interval per subject	STUDYID,USUBJID, CMTRT, CMSTDTC	干预类
CO	Comments	备注	每个受试者每条备注一条记录	One record per comment per subject	STUDYID,USUBJID, COSEQ	特殊用途
DA	Drug Accountability	药物收发记录	每个受试者每个药物收发情况一条记录	One record per drug accountability finding per subject	STUDYID,USUBJID, DATESTCD, DADTC	发现类
DD	Death Details	死亡详情	每个受试者每个发现一条记录	One record per finding per subject	STUDYID,USUBJID, DODESTCD, DDDTC	发现类
DM	Demographics	人口学	每个受试者一条记录	One record per subject	STUDYID,USUBJID	特殊用途
DS	Disposition	受试者分布	每个受试者每个完成状态或每个方案里程碑事件一条记录	One record per disposition status or protocol milestone per subject	STUDYID,USUBJID, DSDECOD,DSSTDTC	事件类
DV	Protocol Deviations	方案偏离	每个受试者每次方案偏离一条记录	One record per protocol deviation per subject	STUDYID,USUBJID, DVTERM,DVSTDTC	事件类
EC	Exposure as Collected	暴露采集	每个受试者每个方案规定的研究用每个采集的用法每个剂量模式一条记录	One record per protocol-specified study treatment, collected-dosing interval, per subject, per mood	STUDYID,USUBJID, ECTRT, ECSTDTC	干预类
EG	Electrocardiogram	心电图	每个受试者每个访视每个时间点每次心电图每个发现一条记录	One record per ECG observation per replicate per time point or one record per ECG observation per beat per visit per subject	STUDYID,USUBJID, EGTESTCD, VISITNUM, EGTPTRF, EGTPTNUM	发现类
EX	Exposure	暴露	每个受试者每个研究药物每个用法一条记录	One record per protocol-specified study treatment, constant-dosing interval, per subject	STUDYID,USUBJID, EXTRT, EXSTDTC	干预类
FA	Findings About Events or Interventions	事件或干预相关发现	每个受试者每个访视每个时间点每个对象每次发现一条记录	One record per finding, per object, per time point, per visit per subject	STUDYID,USUBJID, FATESTCD, FAOBJ,VISITNUM, FATPTREF, FATPTNUM	发现类
HO	Healthcare Encounters	就医事件	每个受试者每次就医事件一条记录	One record per healthcare encounter per subject	STUDYID,USUBJID, HOSTESTCD, HOSTDTC	事件类
IE	Inclusion/Exclusion	不满足的入选/排除标准	每个受试者每条不符合的入选/排除标准一条记录	One record per inclusion/exclusion criterion not met per subject	STUDYID,USUBJID, IETESTCD	发现类
IS	Immunogenicity Specimen Assessments	免疫原性检验	每个受试者每个访视每个检测一条记录	One record per test per visit per subject	STUDYID,USUBJID, VISITNUM, ITESTCD	发现类
LB	Laboratory Data	实验室检查	每个受试者每个访视每个时间点每个实验室检查一条记录	One record per lab test per time point per visit per subject	STUDYID,USUBJID, LBTESTCD,LBSPEC, VISITNUM, LBTPTRF, LBTPTNUM	发现类
MB	Microbiology	微生物检测	每个受试者每个访视每个时间点每个微生物学样本发现一条记录	One record per microbiology specimen finding per time point per visit per subject	STUDYID,USUBJID, MBTESTCD, VISITNUM, MBTPTRF, MBTPTNUM	发现类
MH	Medical History	病史	每个受试者每个发现一条记录	One record per medical history event per subject	STUDYID,USUBJID, MDECOD	事件类
MI	Microscopic Findings	显微镜检查	每个受试者每个样本每个发现一条记录	One record per finding per specimen per subject	STUDYID,USUBJID, VISITNUM, MITESTCD	发现类
MO	Morphology Findings	形态学发现	每个受试者每个访视每个时间点每个部位每个形态学发现一条记录	One record per Morphology finding per location per time point per visit per subject	STUDYID,USUBJID, VISITNUM, MOTESTCD	发现类
MS	Microbiology Susceptibility	药敏试验	每个受试者每个微生物每个药敏试验(或者其他微生物相关发现)一条记录	One record per microbiology susceptibility test (or other organism-related finding) per organism found in MB	STUDYID,USUBJID, MTESTCD,VISITNUM,MSTPTREF, MSTPTNUM	发现类
PC	Pharmacokinetic Concentration	药代动力学浓度	每个受试者每个分析物每个访视每个时间点每个浓度或每个样本特征一条记录	One record per sample characteristic or time-point concentration per reference time point or per analyte per subject	STUDYID,USUBJID, PCTESTCD, VISITNUM, PCTPTREF, PCTPTNUM	发现类
PE	Physical Exam	体格检查	每个受试者每个访视每个身体系统检查或异常情况一条记录	One record per body system or abnormality per visit per subject	STUDYID,USUBJID, PETESTCD,VISITNUM	发现类
PP	Pharmacokinetic Parameters	药代动力学参数	每个受试者每段时间浓度每个建模方法每个PK参数一条记录	One record per PK parameter per time-concentration profile per modelling method per subject	STUDYID,USUBJID, PPTESTCD,PPCAT, VISITNUM, PPPTPTREF	发现类
PR	Procedure	诊疗操作	每个受试者每次诊疗操作一条记录	One record per recorded procedure per occurrence per subject	STUDYID,USUBJID, PRTRT, PRSTDTC	干预类
QS	Questionnaires	问卷与量表	每个受试者每个访视每个时间点每个问卷或量表每语问题一条记录	One record per questionnaire per question per time point per visit per subject	STUDYID,USUBJID, QSCAT,QSTESTCD, VISITNUM, QSTPTREF, QSTPTNUM	发现类
RS	Reproductive System Findings	生殖系统发现	每个受试者每个访视每个时间点每个发现一条记录	One record per finding or result per time point per visit per subject	STUDYID,USUBJID, RPCAT, RPTESTCD, VISITNUM, RPTPTNUM	发现类
RS	Disease Response and Clin Classification	疾病效应/状态评估	每个受试者每个访视每个时间点每个评估者每个评估一条记录	One record per response assessment or clinical classification assessment per time point per visit per subject per assessor per medical evaluator	STUDYID,USUBJID, RSCAT, RSTESTCD, VISITNUM, RSTPTNUM	发现类
SC	Subject Characteristics	受试者特征	每个受试者每个特征一条记录	One record per characteristic per subject	STUDYID,USUBJID, SCTESTCD	发现类
SE	Subject Element	受试者元素	每个受试者每个实际元素一条记录	One record per actual Element per subject	STUDYID,USUBJID, ETCD, SESTDTC	特殊用途
SR	Skin Response	皮肤	每个受试者每个访视每个时间点每个对象每个测试一条记录	One record per finding, per object, per time point, per visit per subject	STUDYID,USUBJID, VISITNUM, SRTESTCD	发现类
SS	Subject Status	受试者状态	每个受试者每个访视每个状态一条记录	One record per finding per visit per subject	STUDYID,USUBJID, STESTCD, VISITNUM	发现类
SU	Substance Use	嗜好品使用	每个受试者每个嗜好品一条记录	One record per substance type per reported occurrence per subject	STUDYID,USUBJID, SUTRT,SUSTDTC	干预类
SV	Subject Visits	受试者访视	每个受试者每个实际访视一条记录	One record per subject per actual visit	STUDYID,USUBJID, VISITNUM	特殊用途
TA	Trial Arms	试验分组	每个试验组每个计划元素一条记录	One record per planned Element per Arm	STUDYID,ARMCD, TAEFORD	试验设计
TD	Trial Disease Assessment	试验疾病评估	每个计划评估期一条记录	One record per planned constant assessment period	STUDYID, TDOORDER, TDANCVAR	试验设计
TE	Trial Elements	试验元素	每个计划元素一条记录	One record per planned Element	STUDYID,ETCD	试验设计
TI	Trial Inclusion/Exclusion Criteria	试验入选/排除标准	每条入选/排除标准一条记录	One record per IE criterion	STUDYID,IETESTCD	试验设计
TR	Tumor/Lesion Results	肿瘤/病灶测量	每个受试者每个访视每个评估者每个评估项一条记录	One record per tumor measurement/assessment per visit per subject per assessor	STUDYID,USUBJID, TRTESTCD, TRCAT, VISITNUM	发现类
TS	Trial Summary	试验概要	每个试验概要参数值一条记录	One record per trial summary parameter value	STUDYID,TSPARMCD, TSSEQ	试验设计
TU	Tumor/Lesion Identification	肿瘤/病灶标识	每个受试者每个标识的肿瘤每个评估者一条记录	One record per identified tumor per subject per assessor	STUDYID,USUBJID, TUTESTCD, TUCAT, VISITNUM	发现类
TV	Trial Visits	试验访视	每个计划每个计划访视一条记录	One record per planned Visit per Arm	STUDYID,VISITNUM, ARMCD	试验设计
TX	Trial Sets	试验群组	每个试验群组每个参数一条记录	One Record per Trial Set Parameter	STUDYID,SETCD, TXPARMCD, TXSEQ	试验设计
VS	Vital Signs	生命体征	每个受试者每个访视每个时间点每个生命体征测量一条记录	One record per vital sign measurement per time point per visit per subject	STUDYID,USUBJID, VSTESTCD, VISITNUM,VSTPTREF, VSTPTNUM	发现类