Business Status -> RMIM attribute mappings

StudySite.accrualStatusCode

As expressed in model COCT_DM000009US

| BRIDG status code | StudySiteClinicalTrialEvent.statusCode | StudySiteAccrualEvent.statusCode | StudySiteAccrualEvent.code |
|----------------------------|--|----------------------------------|----------------------------|
| Not yet Recruiting | new (i.e. pending) | (class not present) | (class not present) |
| Withdrawn | cancelled | (class not present) | (class not present) |
| Recruiting | active | active | TBD#Accrual |
| Enrolling by Invitation | active | active | TBD#AccrualInvitation |
| Active, Not recruiting | active | suspended | TBD#Accrual |
| Not Active, Not Recruiting | suspended | suspended | TBD#Accrual |

Study Site Oversight Status. review Board Process Code

As expressed in model COCT_DM000009US

| BRIDG status code | ClinicalTrialPermissionRequest. actionNegationInd | ClinicalTrialPermission. actionNegationInd | ClinicalTrialPermission. reasonCode |
|------------------------------|---|--|-------------------------------------|
| Review approval not required | true | (class not present) | (class not present) |
| Pending | false | (class not present) | (class not present) |
| Exempt | false | true | Exempt |
| Approved | false | false | (not specified) |
| Denied | false | true | Denied |

DocumentVersionWorkflowStatus.code

As expressed in model COCT_DM000009US

| BRIDG status code | PublicationRequest | PublicationEvent. actionNegationInd | AbstractDocumentEvent | VerificationEvent. value | VerificationEvent. reasonCode |
|-------------------|--------------------|--|-----------------------|--------------------------|-------------------------------|
| Submitted | active | | (doesn't exist) | (doesn't exist) | (doesn't exist) |
| Rejected | completed | true | (doesn't exist) | (doesn't exist) | (doesn't exist) |

| Accepted | completed | false | (doesn't exist) | (doesn't exist) | (doesn't exist) |
|-------------------------|-----------|-------|-----------------|-----------------|-----------------|
| Abstracted | completed | false | (exists) | (doesn't exist) | (doesn't exist) |
| Verification Pending | completed | false | (exists) | (doesn't exist) | (doesn't exist) |
| Abstraction Verified | completed | false | (exists) | true | Response |
| Response | | | | | |
| Abstraction Verified No | completed | false | (exists) | true | No Response |
| Response | | | | | |

StudySubject.statusCode

As expressed in model COCT_DM000003US

| BRIDG status code | StudySubject . statusCode | IdentifiedEntity | EligibilityVerificationEvent. value | ClinicalTrialEvent. statusCode | InterventionEvent .statusCode |
|--------------------|------------------------------|---------------------|-------------------------------------|-----------------------------------|-------------------------------|
| PotentialCandidate | pending | (Class not present) | (Class not present) | (Class not present) | (Class not present) |
| Candidate | pending | (Class present) | (Class not present) | (Class not present) | (Class not present) |
| Withdrawn | cancelled | (Class present) | (Class not present) | (Class not present) | (Class not present) |
| Screening | pending | (Class present) | (not specified) | (Class not present) | (Class not present) |
| Eligible | pending | (Class present) | True | (Class not present) | (Class not present) |
| Pending On-Study | pending | (Class present) | True | new | (Class not present) |
| Ineligible | cancelled | (Class present) | false | (Class not present) | (Class not present) |
| Not Registered | cancelled | (Class present) | true | Cancelled | (Class not present) |
| On-Study | active | (Class present) | true | active | (any) |
| Intervention | active | (Class present) | true | active | active |
| Observation | active | (Class present) | true | active | suspended |
| Follow-Up | active | (Class present) | true | active | completed |
| Off-Study | terminated | (Class present) | true | completed or | (Class not present) |
| | | | | aborted | |

StudyOverallStatus.code

As expressed in model COCT_DM000003US

| BRIDG status code | ClinicalTrialPermission. actionNegationInd | ClinicalTrialEvent.statusCode | AccrualEvent. statusCode | InterventionEvent.statusCode |
|--------------------|--|-------------------------------|--------------------------|------------------------------|
| In Review | (Class not present) | new | | |
| Disapproved | true | new | | |
| Approved | false | new | | |
| Withdrawn | (doesn't matter) | cancelled | | |
| Active | true | active | active | active |
| Temporarily Closed | true | active | suspended | active |
| to Accrual | | | | |
| Temporarily Closed | true | active | suspended | suspended |
| to Accrual and | | | | |
| Intervention | | | | |
| Closed to Accrual | true | active | completed or aborted | active |
| Closed to Accrual | true | active | completed or aborted | completed or aborted |
| and Intervention | | | | |
| Administratively | true | completed | (doesn't matter) | (doesn't matter) |
| Completed | | | | |
| Completed | true | aborted | (doesn't matter) | (doesn't matter) |

${\bf Scheduled Activity. status Code}$

As expressed in model COMT_DM000001US

| BRIDG status code | ScheduledActivity.statusCode | SubstitutionEvent.activityNegationInd |
|--|------------------------------|---------------------------------------|
| Planned | new | (Class not present) |
| Confirmed Within Protocol-Specific Window | new | false |
| Confirmed Outside Protocol-Specific Window | new | true |
| Scheduled | active | (either) |
| Missed | cancelled | (Class not present) |