

| DART_Data | |
|-----------|--------------------------------------------------------------------------------------------------------------|
| PK | <u>DART_UID</u> |
| | ProjectNo ProjectName CaseID DARTDataType DARTLifeCycleStage OriginalFileName DARTFileName |

Example

ProjectNo: 6654, ProjectName: NLST, CaseID: 5708, DARTDataType: Radiology, DARTLifeCycleStage: TBD.

The purpose of this data table is to outline the minimum data elements that each image study needs to come in with. These are captured in the data file itself e.g. DICOM tags or with associated XML or other type of form e.g. if I come in with a NIFTI file what are the additional data elements that it needs to come with to be tagged.

DARTDataType:

- ImageType_DICOM
- ImageType_MINT
- ImageType_NIFTI
- ImageType_XML
- ImageType_JPEG
- ImageType_PNG
- ImageType_DigPath
- ClinicalForm_XML
- ClinicalForm-Text
- Biospecimen
- Genomic
- MEG
- Matlab_Script
- Matlab_DataSet
- R_Script
- R_DataSet
- SAS_Script
- SAS_DataSet

Questions

1. Proposed potential DARTLifeCycleStage elements:

- New
- Submitted
- Resubmitted
- Pending
- PassedQC
- Published

2. How do we tag or name the files so that it carries a universal/GUID:

3. Review of the DART Data Types - what's missing, what should be consolidated?

| Program1 | |
|----------|--------------------------------------------------------------|
| PK | <u>ProgramName</u> |
| | ProgramSponsorOrg ProgramSponsorPerson ProgramCategory |

| Project1 | |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PK | <u>ProjectNo</u> |
| | ProjectProgramOwner ProjectName ProjectShortName ProjectDiseaseSite ProjectActivationDate ProjectTargetAccrual ProjectCloseDate ProjectRequiresTRIADFlag UpdateDate |

Example

ProgramCategory: NCI Trials, ProgramName: ECOG-ACRIN, ProgramSponsorOrg: NCI
ProjectNo: 6654, ProjectName: NLST, ProjectProgramOwner: ECOG-ACRIN

Questions

1. How do we reconcile the Project data elements with the ECOG-ACRIN Study data elements in the common classes?
2. Are there any other project attributes we should add?
3. Where do we put the audit data elements? Do we need to track these elements e.g. CreationDate, UpdateDate
4. How do we tie the fact that ProjectProgramOwner should be the same as ProgramName?

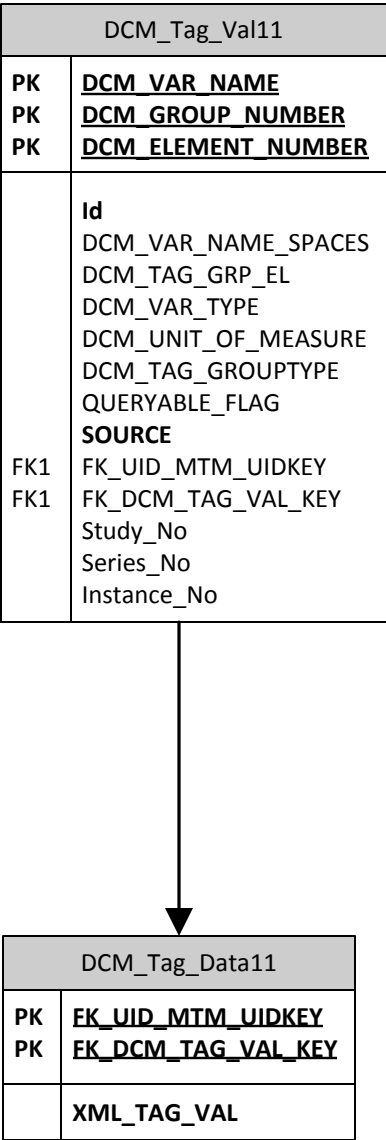
These data elements are in the ECOG-ACRIN common classes, so how do we reconcile?

| DimStudy2 | |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PK | <u>StudyKey</u> |
| I1 | StudyAlternateKey StudyNo StudyNCIProtocolNo StudyNCTNo StudyCooperativeGroupProtocolNo StudyName StudyShortName StudyRaveName StudyProjectOwner StudyPrimaryFunding StudyDivision StudyPhase StudyTreatmentType StudyTreatmentTypeCode StudyChair StudyCommittee StudyTargetAccrual StudyConceptApprovalDate StudyConceptApprovalDateSOURCE StudyProtocolApprovalDate StudyVersionDate StudyPrimaryCompDate StudyActivationDate StudyActivationDateKey StudyNCIActivationDate StudyCloseDate StudyCloseDateKey StudyTerminateDate StudyTerminateDateKey StudySuspensionDate StudyReactivationDate StudyCTCVersion StudyDiseaseSite StudyBlindedFlag StudyRandomizedFlag StudyRequiresTRIADFlag StudyCoordinatingAccrualGroup StudyCommitteeSOURCE StudyPhaseSOURCE StudyDivisionSOURCE StudyPrimaryFundingSOURCE StudyProjectOwnerSOURCE StudyTreatmentTypeSOURCE StudyCoordinatingAccrualGroupSOURCE StudyCTCVersionSOURCE StudyDiseaseSiteSOURCE |
| I1 | EffectiveDate ExpirationDate CurrentFlag CreationDate UpdateDate UpdateProcess |
| I1 | Source |

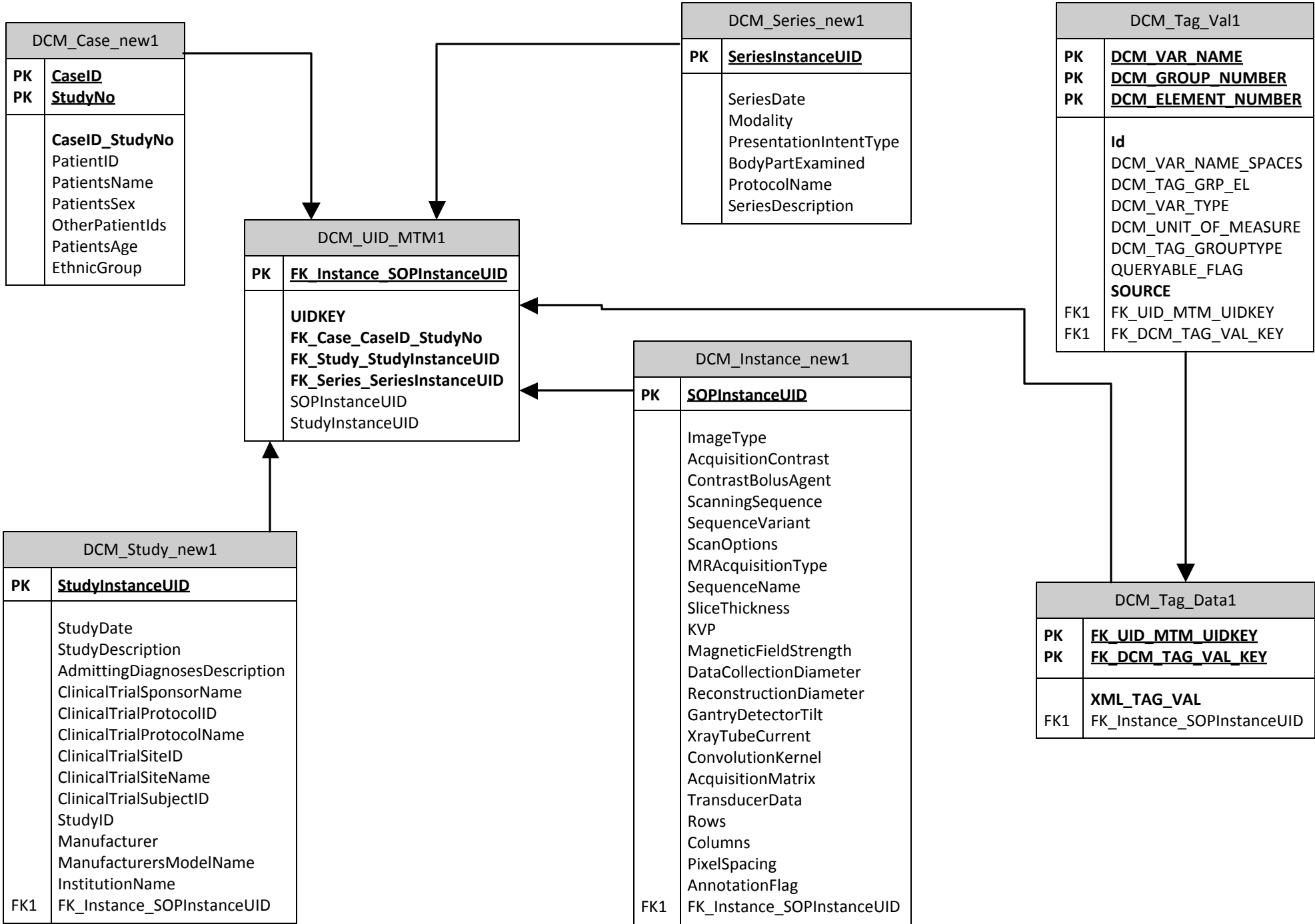
| ClinicalForm1 | |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PK | <u>FormCode</u> |
| | StudyName StudyNo SiteName CaseNo CaseRecordNo FormName FormDescription **FormCategory FormDueDate QNum QuestionDescription QuestionResponse QuestionResponseDescription_num QuestionResponseDescription_boolean QuestionResponseDescription_text |

Questions on the model:

1. FormDueDate came from CTDW – should this be FormSubmittedDate? Need to verify. Or do we track FormDueDate and FormSubmittedDate?
2. It is not clear what the CaseRecordNo means?
3. Global question – StudyName should be changed to ProjectName?
4. Suggest change – ‘QuestionResponse’ to ‘QuestionResponseValue’
5. FormCategory – we used this to classify form as demographic, radiology, pathology, etc. in early Clinical Form Search Tab. Do we need to tag forms like this moving forward?
6. Is Elasticsearch ‘_index’ e.g. ‘eadw’ and Elasticsearch ‘_type’ e.g. ‘record’ needed in the model or are these just Elasticsearch ingested values
7. Are we missing any other key attributes to describe Clinical Forms e.g. Connectome



- Questions
1. ACR BAH Team identified top 50 DICOM tags that may be useful to directly query on, and created an ACR assignment to study series instance across segments (see specific tablse). All the other elements, including the top 60, could be accessed through DCM_Tag_Val1. Note: this was applied to only one instance from one series at a time (e.g. image #5 of a series). Do we keep the top 60 or do we just use DCM_Tag_Val1 table with case information, etc.
 2. How would we create a MINT/MICA version of this data model? We would receive one large file with all the unique tags at the study, series, instance levels.



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| DARTUserAccount | |
|-----------------|------------------------------------------------------------------------------------------------------------------------------|
| PK | <u>UserAccountID</u> |
| | FirstName LastName Address Phone InstitutionName Department JobTitle EmailAddress AdditionalComments |

Note: EADW (Ravi) is working on a Person model which will be in this spot to compare/reuse as it becomes a common class.