

documentation described in the document logical classification. For example, a piece of documentation that describes the manufacturer would have a coded keyword of "manufacturer" and the name of the manufacturer in freeform text. (Same as Release 1)

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	textExplanation	ED							Specific text value associated with the coded keyword in the specific context of the keyword associated with the document logical classification.

Relationships

Columns	Association	Notes
	1 ContextOfUse. 0..* AssociatedKeyword.	
	1 KeywordDefinition. 0..* AssociatedKeyword.	

ContextOfUse

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 10/17/2008. Last modified on 2/10/2009.

Notes: A means of grouping documents for assignment, review, structure (i.e., of electronic files within a larger whole), descriptive document type (e.g., synopsis, manufacturing methods) etc. The type would indicate whether the group is a table of contents/context of use descriptor, etc.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	classificationTypeCode	CD							Specifies the code and code set of the classification type.
	languageCode	CD							Language of the document logical classification.
	status	CD							Status code of the specific document logical classification (e.g., active).

Relationships

Columns	Association	Notes
has associated	1 DocumentLogicalClassification. 0..* ContextOfUse.	
adds or modifies	1 DocumentReference. 0..* ContextOfUse.	
	1 ContextOfUse. 0..* AssociatedKeyword.	

DocumentFile

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 10/30/2008. Last modified on 10/30/2008.

Notes: Any metadata associated with the documentation including an associated electronic file (optional).
A message could refer to a previously sent electronic file without sending it again.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	Country	CD							This is the country that the document relates to.
	description	ED							Text description of the document file (optional).
	fileName	ST							Filename of the specified file.
	languageCodes	SET<CD >							The language of the document file. This can be a repeating attribute that allows one or many languages to be defined. This is a RPS R2 - Flexibility point.
	location	ED							A text description of the location of the document file.
	mediaType	CS							File type of the associated electronic file.
	revision	INT							The revision of the document file.

Relationships

Columns	Association	Notes
acts upon	1..* DocumentReference. 0..* DocumentFile.	Needs explanation
references (main)/referenced by	0..* DocumentReference. 0..1 DocumentFile.	

DocumentReference

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 10/16/2008. Last modified on 11/12/2008.

Notes: A reference to a document accompanying a submission unit.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	associatedActionCode	CD							Coded value that specifies the action the recipient should perform on the referenced document (add, remove, append, etc.).
	comment	ED							Freeform text comment that describes the reference (optional).

Relationships

Columns	Association	Notes
directs the document toward one or more intended targets	1 DocumentReference. 0..* DocumentationTarget.	
	1 DocumentReference. 0..* DocumentLogicalClassification.	
adds or modifies	1 DocumentReference. 0..* ContextOfUse.	
acts upon	1..* DocumentReference. 0..* DocumentFile.	Needs explanation
references (main)/referenced by	0..* DocumentReference. 0..1 DocumentFile.	
contains	1 SubmissionUnit. 0..* DocumentReference.	

DocumentationTarget

Database: Java, *Stereotype:* «StudyRelationship», *Package:* BRIDG Domain Model

Detail: Created on 10/21/2008. Last modified on 11/12/2008.

Notes: Associates the document reference (and the document file by inference) with specific regulatory authorities.

Relationships

Columns	Association	Notes
is a recipient of/receives	1 RegulatoryAuthority. 0..* DocumentationTarget.	
directs the document toward one or more intended targets	1 DocumentReference. 0..* DocumentationTarget.	

KeywordDefinition

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 10/17/2008. Last modified on 11/12/2008.

Notes: Keyword Definitions are a set of coded values constrained by the regulatory application.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	code	CD							Keyword definition concept descriptor specifying the code, code system, display value, etc.

Relationships

Columns	Association	Notes
	<anonymous>. KeywordDefinition.	
	1 KeywordDefinition. 0..* AssociatedKeyword.	
	1..* RegulatoryApplication. 0..* KeywordDefinition.	

OrganizationContactPerson

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 10/17/2008. Last modified on 11/25/2008.

Notes: Person who serves as a contact for the organization and associated contact information.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	contactMethods	SET<URL>							Types and values for e-mail addresses, telephone numbers, web sites, etc., associated with the contact person.
	personName	PN							A name for a person. A sequence of name parts such as family name, prefix, suffix, etc.
	postalAddress	AD							Address of the contact person if different from the organization address.
	roleCode	CV							
	roleComment	ED							Clarification of the role beyond that implied by the coded value.
	status	CD							The status of the person's association with the organization.

Relationships

Columns	Association	Notes
	1 Organization. 0..* OrganizationContactPerson.	
	0..* personContactMethod. 1 OrganizationContactPerson.	
	1 OrganizationContactPerson. 0..* SubmissionContactPerson.	
	1 OrganizationContactPerson. 0..* SubmissionUnitContactPerson.	

RegulatoryApplicationSponsor

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 2/23/2009. Last modified on 2/23/2009.

Notes:

Relationships

Columns	Association	Notes
SponsorOrganization	RegulatoryApplicationSponsor. Organization.	
	RegulatoryApplicationSponsor. RegulatoryApplicationSponsor.	

RegulatorAssessment*Database:* Java, *Stereotype:* , *Package:* BRIDG Domain Model*Detail:* Created on 1/14/2009. Last modified on 1/14/2009.*Notes:* Supports regulator assessments (regulatoryAssessmentCode) from many regulators. A regulator assessment can apply to a submission, a relationship between a submission and regulated product or both.**Columns**

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	regulatoryAssessmentCode	int							<p>A regulatory designation made by the regulatory authority.</p> <p>For example, the submission can either be active, withdrawn, approved, not approvable, approvable, complete response or cleared.</p> <p>NOTE: For some submissions, there are business processes that will make "default" action based on timelines --i.e., if no action is taken, then the submission is "approved".</p> <p>NOTE: For a submission, there may be multiple regulatory assessments that correspond to the state transitions for a submission, but only one regulatory assessment is true at a given time. A submission can first be "approvable" and then when the data is complete, a new regulatory assessment can be made that is "approved".</p>
	regulatoryAssessmentDate	int							The date the regulator recorded the regulatoryAssessment Code.
	regulatoryAuthorityID	int							

Relationships

Columns	Association	Notes
	1 Organization.makes * RegulatorAssessment.madeBy	
	0..1 SubmissionRegulatedProductRelationship.assessedb y * RegulatorAssessment.assesses	
	0..1 Submission.assessedBy * RegulatorAssessment.assesses	

RegulatoryApplicationSponsor

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 2/23/2009. Last modified on 2/23/2009.

Notes:

RegulatoryAuthority

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 2/23/2009. Last modified on 2/23/2009.

Notes:

Relationships

Columns	Association	Notes
RAOrganization	RegulatoryAuthority. Organization.	
	RegulatoryAuthority. RegulatoryAuthority.	

RegulatoryAuthority

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 2/23/2009. Last modified on 2/23/2009.

Notes: Governmental bodies that have the power to pass and enforce laws.

For example, the Medicines and Healthcare Products Regulatory Agency (MHRA) in UK, the Food and Drug Administration (FDA) in the USA.

Relationships

Columns	Association	Notes
	RegulatoryAuthority. Organization.	

SubmissionContactPerson

Database: Java, *Stereotype:* «StudyRelationship», *Package:* BRIDG Domain Model

Detail: Created on 11/25/2008. Last modified on 11/25/2008.

Notes: Associates the contact persons with submissions and describes that person's contact role for that submission.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	roleCode	CV							The role that the

									person from the organization plays for the Submission.
	roleComment	ED							
	status	CD							The status of the association of the contact with the Submission.

Relationships

Columns	Association	Notes
	1 OrganizationContactPerson. 0..* SubmissionContactPerson.	
	1 Submission. 0..* SubmissionContactPerson.	

SubmissionRegulatedProductRelationship

Database: Java, *Stereotype:* «StudyRelationship», *Package:* BRIDG Domain Model

Detail: Created on 10/17/2008. Last modified on 11/13/2008.

Notes: Relationship between submissions and regulated products.

(Resolved many-to-many relationship). Especially for devices, the Submission (aka Regulatory Activity) may apply to many products and vice versa.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	dateRange	int							

Relationships

Columns	Association	Notes
	1 RegulatedProduct. 0..* SubmissionRegulatedProductRelationship.	
	1 Submission. 0..* SubmissionRegulatedProductRelationship.	
	0..1 SubmissionRegulatedProductRelationship.assessedb y * RegulatorAssessment.assesses	

SubmissionUnitContactPerson

Database: Java, *Stereotype:* «StudyRelationship», *Package:* BRIDG Domain Model

Detail: Created on 11/12/2008. Last modified on 2/10/2009.

Notes: Organizations receiving the Submission Unit.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	recipientRole	CD							Role of the recipient (e.g., main, cc, FYI).

Relationships

Columns	Association	Notes
	0..* SubmissionUnitContactPerson. 1 SubmissionUnit.	
	1 OrganizationContactPerson. 0..* SubmissionUnitContactPerson.	

personContactMethod

Database: Java, *Stereotype:* , *Package:* BRIDG Domain Model

Detail: Created on 10/17/2008. Last modified on 11/13/2008.

Notes: Specific contact method (e.g., e-mail address, phone number) for the organization contact person.

Columns

PK	Name	Type	Not Null	Unique	Len	Prec	Scale	Init	Notes
	typeCode	CV							A coded value indicating the type of contact method (e.g., phone, fax, e-mail).
	value	ED							Specific value for the

Relationships

Columns	Association	Notes
	0..* personContactMethod. 1 OrganizationContactPerson.	