```
<name use="IDE">
  <family> patient's family name</family>
  <given> patient's given name</given>
</name>
```

- Romanized spelling: (option) It shall be used to support equipment whose Japanese language processing capability is not sufficient.

```
<name use="ABC">
  <family> Romanized spelling of patient's family name</family>
  <given> Romanized spelling of patient's given name</given>
</name>
```

Note: When a family name and a given name cannot be separated, both names shall be put in the family name field. A middle name shall be put in the given name field.

Address

It shall be described by PatientRole.addr.

- TO, DO, FU, KEN shall be described by <state>.
- SHI and 23 KU of TO, GUN shall be described be <city>.
- KU, MACHI, MURA, CHO, AZA, BANCHI, etc. shall be described by <streetName>.
- Postal code number shall be described with <postalCode>.
- Japan shall be described as <country>JP </country>.

```
<addr>
   <country>JP</country>
   <postalCode>postal code number</postalCode>
   <streetName> KU, MACHI, MURA, CHO, AZA, BANCHI</streetName>
   <city> SHI, KU, GUN</city>
   <state>TO, DO, FU, KEN </state>
</addr>
```

Telephone number

It shall be described by PatientRole.telecom. All telephones or FAX numbers shall be coded in form (RFC2806) such as tel: or fax:URLschema. An international phone call shall be described by the country code (for example, +81 for Japan), followed by the dial number. For legibility, it may include a separator.

- Audio telephone number shall be described by prefix tel:
- FAX number shall be described by prefix fax:
- E-mail shall be described by "mailto"

Telephone classification shall be described by the USE attribute.

- H: Home
- WP: Workplace

- EC: Emergency connection
- MC: Mobile connection

<telecom use=" telephone classification "value=" tel: telephone number "/>

Occupation, hobby, etc.

It shall describe information about the occupation and general information. The occupational career directly related to disease shall be described in the body.

The <desc> occupation, office worker </desc>

Gender (administrativeGenderCode)

It is HL7 gender code (2.16.840.1.113883.5. 1), which shall be described by Administrative Gender.

F	Female
M	Male
UN	Unknown

<administrativeGenderCode code="gender" codeSystem=" HL7 gender code (2.16.840.1.113883.5. 1) "/>

Age

This standard does not directly describe the age, but it shall be calculated by the difference between the date of birth and the date of description (Author.time).

Date of birth (birthTime)

It shall be described by YYYYMMDD.

CDA describes the date of birth by A.D. display (YYYYMMDD). When the implementation system describes it by the Japanese calendar, the style sheet etc. shall convert the internal display (A.D.) into the Japanese calendar display.

MEIJI	1868−09−08	to	1912−07−29
TAISHO	1912−07−30	to	1926−12−24
SHOWA	1926−12−25	to	1989−01−07
HEISEI	1989−01−08	to	

<birthTime value= "birth date"/>

5.2.3. Information recipient (informationRecipient)

The diagnosis information recipient shall be described by informationRecipient.

Figure 5 Information recipient (informationRecipient)

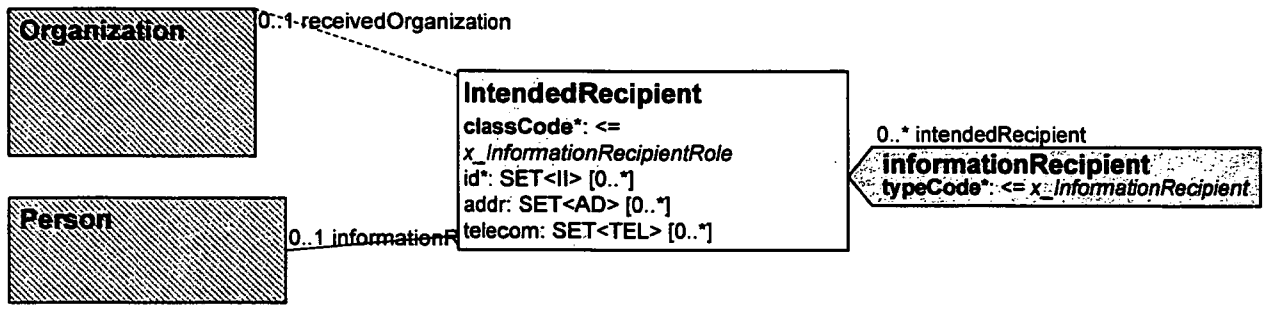


Table 3 Information recipient HMD

informationRecipient	0..*			SET<InformationRecipient>		
typeCode	1..1	M	R	CS	x_InformationRecipient	CNE
intendedRecipient	1..1			IntendedRecipient		
classCode	1..1	M	R	CS	x_InformationRecipientRole	CNE
id	0..*		R	SET<II>		
addr	0..*			SET<AD>		
telecom	0..*			SET<TEL>		
informationRecipient	*0..1*			*Person*		
name	0..1			SET<PN>		
receivedOrganization	*0..1*			*Organization*		
id	0..1			SET<II>		
name	0..1			SET<ON>		

(1). The information recipient shall be described by (informationRecipient).

```
<informationRecipient typeCode="PRCP">
 <intendedRecipient classCode="ASSIGNED">
  <id extension="information recipient ID" root=" information recipient organization UID"/>
```

Information recipient address

```
    <addr>
      <country>JP </country>
      <postalCode> postal code number </postalCode>
      <streetName> KU, MACHI, MURA, CHO, AZA, BANCHI </streetName>
      <city> SHI, KU, GUN </city>
      <state> TO, DO, FU, KEN </state>
    </addr>
```


Information recipient organization telephone number

```
<telecom use="WP"value=" tel: telephone number "/>
```

Information recipient doctor name

```
<informationRecipient>
   <name use="IDE">
      <family> family name </family>
         <given> name </given>
   </name>
</informationRecipient>
```

Information recipient medical institution name

```
<receivedOrganization>
   <id extension="medical institution ID" root=" medical organization UID"/>
   <name> information recipient medical institution/organization name </name>
</receivedOrganization>
```


5.2.4. Author, patient referral document creator (author)

Information about the doctor and medical institution that creates the patient referral document shall be described.

Figure 6 Author

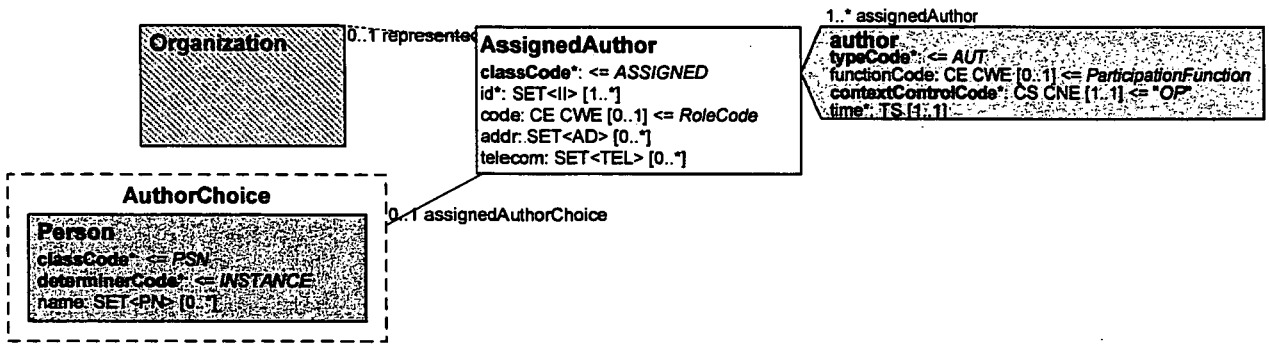


Table 4 Author HMD

author	1..*			SET<Author>		
typeCode	1..1	M	R	CS	AUT	CNE
functionCode	0..1			CE	ParticipationFunction	CWE
contextControlCode	1..1	M	R	CS	OP	CNE
time	1..1		R	TS		
assignedAuthor	1..1			AssignedAuthor		
classCode	1..1	M	R	CS	ASSIGNED	CNE
id	1..*		R	SET<II>		
code	0..1			CE	RoleCode	CWE
addr	0..*			SET<AD>		
telecom	0..*			SET<TEL>		
assignedAuthorChoice	0..1			Person | AuthoringDevice		
assignedPerson	*1..1*			*Person*		
name	1..1			SET<PN>		

(1). The information that creates the patient referral document shall be described by (author).

```
<author>
    <time value= "patient referral document creation date and time"/>
    <assignedAuthor>
    < id extension="creator ID" root=" UID to which creator belongs"/>
```


The creation time (time) is usually the same as the time of issue of the patient referral document.

The patient referral document creator and the author address shall be described.

```
<addr>
   <country>JP </country>
   <postalCode> postal code number </postalCode>
   <streetName> KU, MACHI, MURA, CHO, AZA, BANCHI </streetName>
   <city> SHI, KU, GUN </city>
   <state> TO, DO, FU, KEN </state>
</addr>
```

The patient referral document creator, the author telephone number

```
<telecom use="WP"value=" tel: telephone number "/>
```

The patient referral document creator, the referral doctor

```
<assignedPerson>
   <name use="IDE">
      <family> referral doctor's family name </family>
      <given> referral doctor's given name </given>
   </name>
</assignedPerson>
```

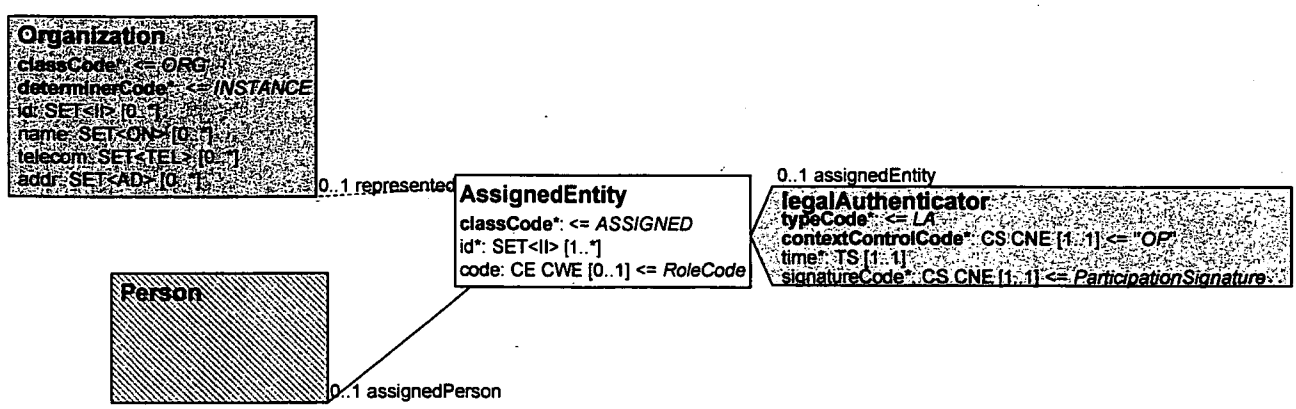
The patient referral document creator, the author medical institution

```
<representedOrganization>
   <name> medical institution name </name>
</representedOrganization>
```

Legal authenticator

The person and organization responsible for the patient referral document shall be described by legalAuthenticator.

Table 5 Legal authenticator



legalAuthenticator	0..1	LegalAuthenticator

typeCode	1..1	M	R	CS	LA	CNE
contextControlCode	1..1	M	R	CS	OP	CNE
time	1..1		R	TS		
signatureCode	1..1		R	CS	ParticipationSignature	CNE
assignedEntity	*1..1*			*AssignedEntity*		
id	1..*		R	SET<II>		
code	0..1			CE	RoleCode	CWE
assignedPerson	*0..1*			*Person*		
name	0..1			SET<PN>		
representedOrganization	*0..1*			*Organization*		
id	0..1			SET<II>		
name	0..*			SET<ON>		
telecom	0..*			SET<TEL>		
addr	0..*			SET<AD>		

5.2.5. Other common information

(1). Custodian

This description is essential in the original CDA standard. But, at the time of creating the patient referral document, this custodian is not clearly appointed, and the responsible person to provide information does not know who is the responsible (information recipient). So, if the original standard is to be followed, the description should be nullFlavor. But, this standard dares to make the description optional.

dataEnterer

When persons other than the creator enter the data, it shall be described by dataEnterer.

LegalAuthenticator

CDA standard describes (Authenticator). This standard recommends that all should be authenticated including the accompanying documents. So, it is outside the scope of this standard.

5.3. Patient referral document body

The description about the provision of diagnosis information shall be described in CDA standard body (component.structuredBody) for every description item in sections.

Figure 7 Patient referral document body (component.structuredBody)

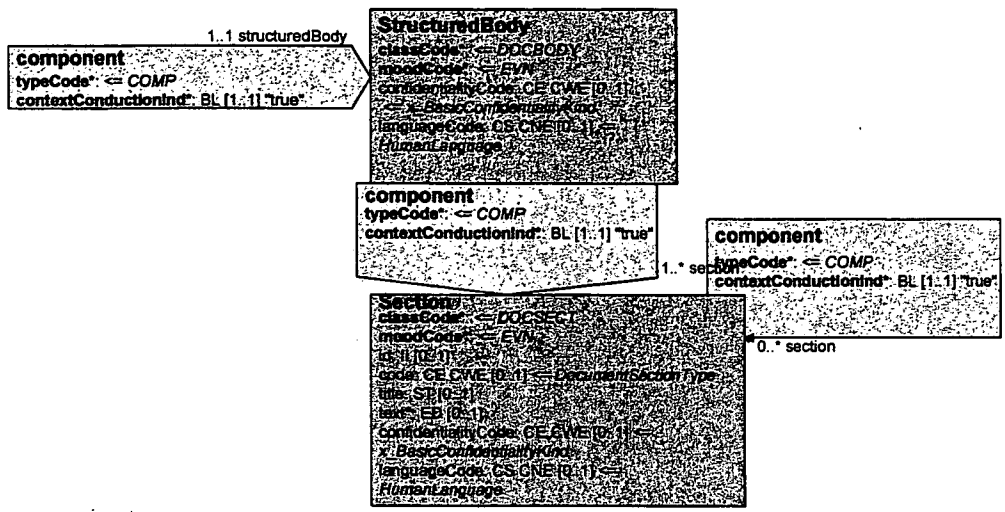


Table 6 HMD of body

structuredBody	1..1			StructuredBody		
confidentialityCode	0..1			CE	x_BasicConfidentialityKind	CWE
component	1..*			SET<Component3>		
contextConductionInd	1..1	M	R	BL		
section	1..1			Section		
id	0..1			II		
code	0..1			CE	DocumentSectionType	CWE
title	0..1			ST		
text	0..1		R	ED		
confidentialityCode	0..1			CE	x_BasicConfidentialityKind	CWE
entry	0..*			SET<Entry>		
typeCode	1..1	M	R	CS	x_ActRelationshipEntry	CNE
contextConductionInd	1..1	M	R	BL		
clinicalStatement	1..1					

Note 1: For this patient referral document specification V1.0, description of body is mostly specified at the level 2, except for a few exceptions. This is because the standardization system

and the standard code are not fully disseminated in Japan as of the year 2007. Accordingly, the main part of the description consists of a subject name and a description section written in natural language.

Note 2: This patient referral document specification V1.0 does not use NonXMLBody in CDA standard.

When application of these items is difficult, a description without a subject name (level 1) is allowed.

5.3.1. Description rule

(1). The start of the body part

The body part shall be described by component.structuredBody.

```
<component contextConductionInd="true">  <structuredBody>
        Each text
```

Item name

Each item consists of an item code and its description section.

- The start section of description: Each description item shall be described by the start section:

```
<component contextConductionInd="true">
  <section>
```

- Item name: The item name shall be shown by its code (code) and its reading (displayName). The subject name complies with CDA standard, and uses the subject name described in the title section.

```
<code code="item JMIX code" codeSystem=" JMIX UID(1.2.392.200119.5.3.1)
"codeSystemName="JMIX" displayName=" item name "/>
        <title> item name </title>
```

- Statement: The statement shall be described in natural language.

```
<text>natural language or description with sentences controlled HTML format </text>
```

Note: CDA standard states that the human-readable description section (text) shall be duplicated with the level 3 description section (ClinicalStatement) of the computer-processing section. This standard specifies that both descriptions shall be readable and computer-processed, and does not require duplication. This is based on the following policy. Namely, description in natural language

is indispensable also in the future. On the other hand, even the computer-processing section written in the ClinicalStatement section should be readable to personnel including medical workers.

- Format control: In the description section, the HTML's format control based on CDA standard 4.3.5 is possible.

Description in ClinicalStatement (level 3)

When a computer performs automatic processing etc., ClinicalStatement shall be used for description. This standard V1.0 does not require description by ClinicalStatement except for the physical findings and other numerical sections. It is hoped that future progress in standard code and system standardization enables description by ClinicalStatement.

Attached papers

Various examination data etc. shall be associated by URI reference by the external document (externalDocument) or the external observation (externalObservation). These are exceptionally described by using the CliniclaStatement section, even if there is no body description of the ClinicalStatement section. On the occasion of reference to an external document, in order to ensure authenticity, this standard recommends SHA-1 hash code IntegrityCheck, which is V3 standard rule.

Figure 8 Attached papers (external reference)

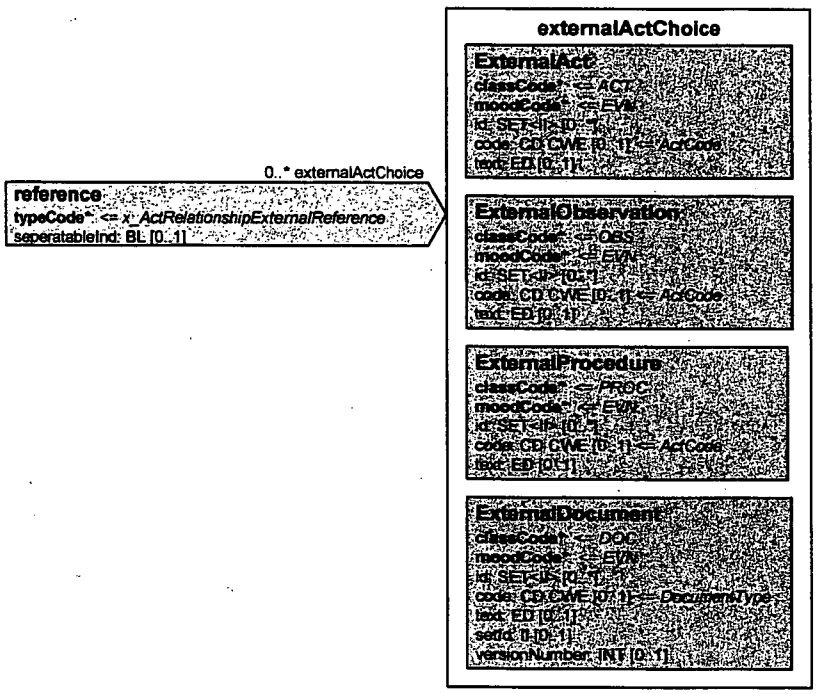


Table 7 External reference document HMD

reference	0..*			SET<Reference>		
typeCode	1..1	M	R	CS	x_ActRelationshipExternalReference	CNE
externalActChoice	1..1			ExternalAct | ExternalObservation | ExternalProcedure | ExternalDocument		
externalAct	1..1			ExternalAct		
id	0..*			SET<II>		
code	0..1			CD	ActCode	CWE
text	0..1			ED		
externalObservation	1..1			ExternalObservation		
id	0..*			SET<II>		

code	0..1			CD	ActCode	CWE
text	0..1			ED		
externalProcedure	1..1			ExternalProcedure		
id	0..*			SET<II>		
code	0..1			CD	ActCode	CWE
text	0..1			ED		
externalDocument	1..1			ExternalDocument		
id	0..*			SET<II>		
code	0..1			CD	DocumentType	CWE
text	0..1			ED		
setId	0..1			II		
versionNumber	0..1			INT		

```
<component contextConductionInd="true">
  <section>
    <code ..... />
    <title> .... .. </title>
    <text/>
    <entry contextConductionInd="true">
      <observation classCode="OBS" moodCode="EVN">
      <code ...../>
        <reference typeCode="SPRT">
        <externalDocument>
          <code ...../>
          <text mediaType= "MIME"representation=" B64"integrityCheck=" SHA-1 hash code" >
            <reference value= "attached file URI"/>
          </text>
        </externalDocument>
```

For attached papers, the following standardized documents shall be used.

- Clinical-examination data: Laboratory tests etc. are documents described by HL 7 V2.5.
- Images: Radiological images etc. are documents described by DICOM. However, DICOM standard is not practical for schema, etc. In that case, general industrial standards, such as JPEG, are permitted.
- Medical waveforms: Medical waveforms, such as ECG and brain waves, are documents described by MFER (ISO/TS 11073-92001).
- For other documents, such as records by scanning paper documents, and documents that cannot be described by the above-mentioned standard, attachment by PDF is also permitted.

5.3.2. Description item

The following are typical description items. Note that these are merely typical and do not put limitations to the implementation site.

Table 8 List of description items

Item name	Vocabulary	JMIX code	Remarks
Patient referral document	Explanation of the provided information	MD0020730	
Purpose	Purpose of information provision	MD0020200	It is used also as explanation of the provided information.
Disease-and-injury name and chief complaint	Chief complaint	MD0018530	
Present disease, diagnosis, name	The present disease diagnostic name	MD0022790	
History of present disease	History of present disease	MD0018550	
Anamnesis	Anamnesis	MD0014230	
Allergy	Allergy information	MD0014760	
Family history	Family history	MD0014860	
Physical findings	Physical findings	MD0018730	
Infection	Existence of an infection factor	MD0015320	
Lifestyle and risk factor	Lifestyle	MD0012990	
Vaccination	Vaccination name	MD0013820	
Operation	Operation implementation record information	MD0020890	
Transfusion record	Previous transfusion history	MD0014330	
Present prescription and present medication information	Present medication prescription directions Present medication, prescription directions	MD0022780	
Examination result	Examination result	MD0018800	
Treatment	Treatment implementation record information	MD0020900	
Insurance information	Information provision insurance classification	MD0020210	
Occupational history	Occupational history	MD0012810	
Remarks, communication	Information author communication remarks	MD0020330	
Attached papers			Description of examination etc. is indicated as an external document.

(1). Purposes MD 0020200 (referral purpose etc.)

This section describes the purpose (Purpose) of providing diagnostic information. When providing a patient with this diagnostic information, it is not necessary to describe the purpose clearly.

(2). Disease-and-injury name and chief complaint MD 0018530

These sections describe the patient's disease-and-injury name.

(3). The present disease (the contents of the disease, the history of present disease, the progress of symptoms) MD0022790 and MD0018550

This section describes the findings (summary of medical examination) and the present disease (diagnostic contents, history of present disease) including the progress of symptoms.

(4). Anamnesis MD 0014230

This section describes the anamnesis that was experienced by the patient.

(5). Allergy MD 0014760

This section describes the patient's allergies. It describes all allergies, adverse reactions, hypersensitivity, etc. This section may describe allergen, induction-related information, and a comment.

Allergies includes to medicine, food, and other allergies. Although a patient notified an allergy to penicillin, a skin test proved negative. Such cases should be described also.

(6). Hospitalization history

This section describes all related previous medical examinations in reverse chronological order.

(7). Family history MD 0014860

This section describes any family history to which the patient is related. This section describes the cause of death etc. of a family member.

(8). The reason for visit to hospital

This section describes the reason for the visit to hospital (Reason For Visit).

(9). Physical findings MD 0018730

This section describes any information related to the patient's physical findings (General status, Physical Findings/Examination Measurements). The patient's vital signs are also described in this section.

(10). Infection

This section describes any infection. It describes the items that the information recipient wants to know concretely. If necessary, it describes any existence of infection and refers to "infection name: none, so-and-so, unknown. Severity. Date of confirmation".

(11). Lifestyle / risk factor MD 0012990

This section describes the patient's social history (lifestyle / risk factor). Related dates or any additional comments should be shown.

(12). Vaccination MD 0013820

This section lists any vaccinations and the date of medication in reverse chronological order. This section is arbitrary. However, it is recommendable for pediatrics. On the other hand, if the information is known, it should be described.

(13). Operation and treatment MD 0020890

This section describes any history of operations. It should describe the name and date of related treatment in reverse chronological order.

(14). Transfusion record MD 0014330

This section describes any record of transfusions.

(15). The present prescription MD 0022780

This section describes any present prescriptions.

Note: The data of a required related prescription history shall be attached as external data.

(16). The degree of necessity of care

This section describes the degree of necessity of any care to which the patient is related. It describes the situation of the degree of everyday life independence, care need assessment etc.

(17). Therapy plan

This section describes a therapy plan including any treatment of the patient. Furthermore, it describes a detailed schedule of implementation including any change of hospital.

(18). Prior instructions

This section describes prior instructions, a will, a legal representative, donor intention manifestation and other reference documents related to information about the patient. (They shall be attached as external documents.)

(19). Examination information MD 0018800

In this standard, the text and value of examination results, findings are described, and any external object is linked as an attached file. Namely, reference is made to external objects such as external images and existing reports. Each object has an id and code, and can be referred to by designating MIME type.

Note: In the case of CDA R2, reference to an external object is possible with NonXMLBody and ObservationMedia. But, this standard uses external reference (reference).

・ Examination

This section describes the contents of examinations and findings. The detailed data of the examination is written in text and becomes an attached file. The recommended code system is JC10 (JLAC10).

・ Image

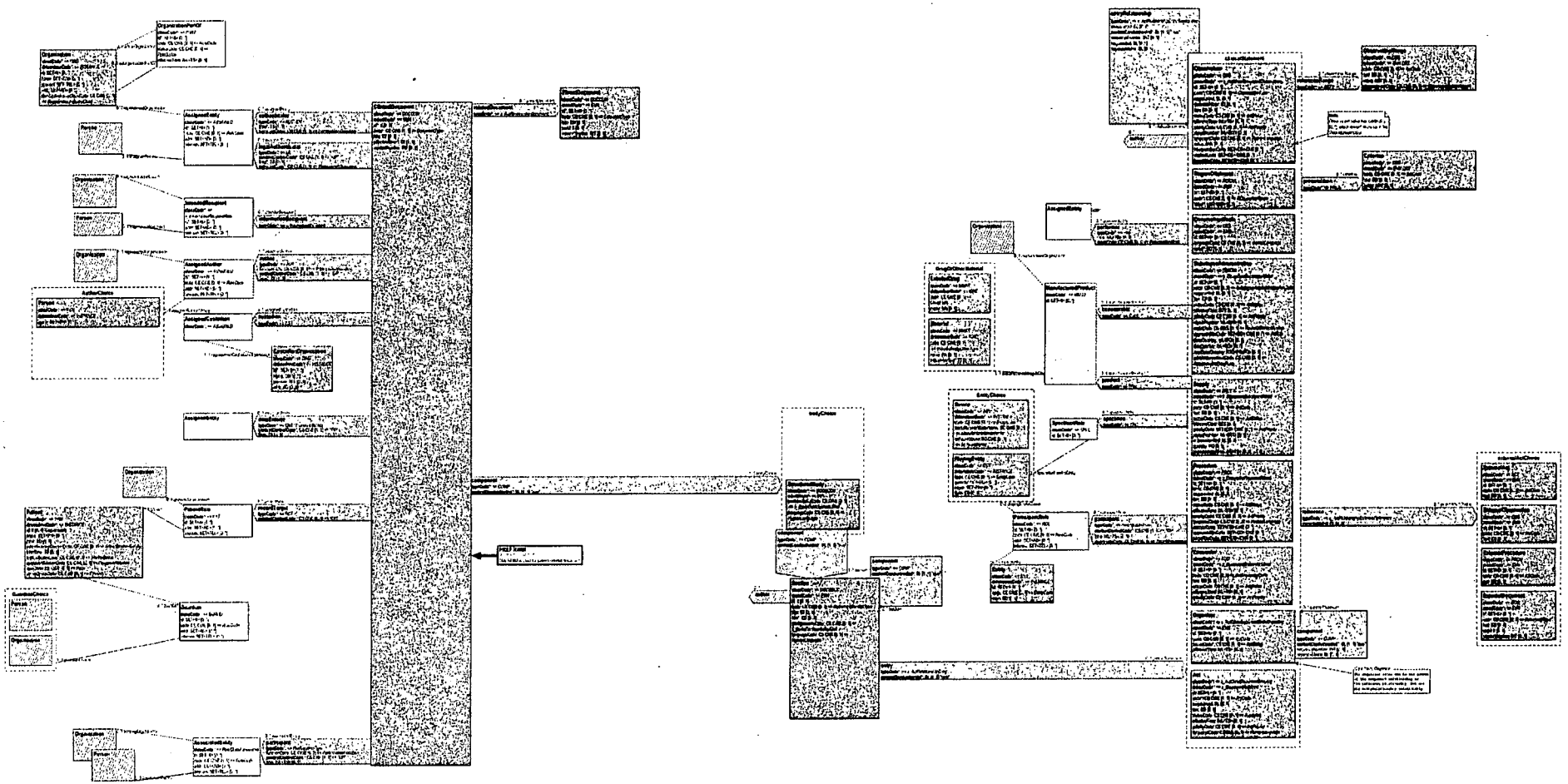
This section describes image data. Image data is attached as external reference.

(20). Remarks MD 0020330

This section describes any communication and precautions.

Attached document　Patient referral document

In this R-MIM, restrictions are applied to R-MIM to use CDA R2 R-MIM for a patient referral document.



【資料３】

CRF作成支援システム　CR+

臨床研究支援ソリューション

CRF作成支援システムCR+

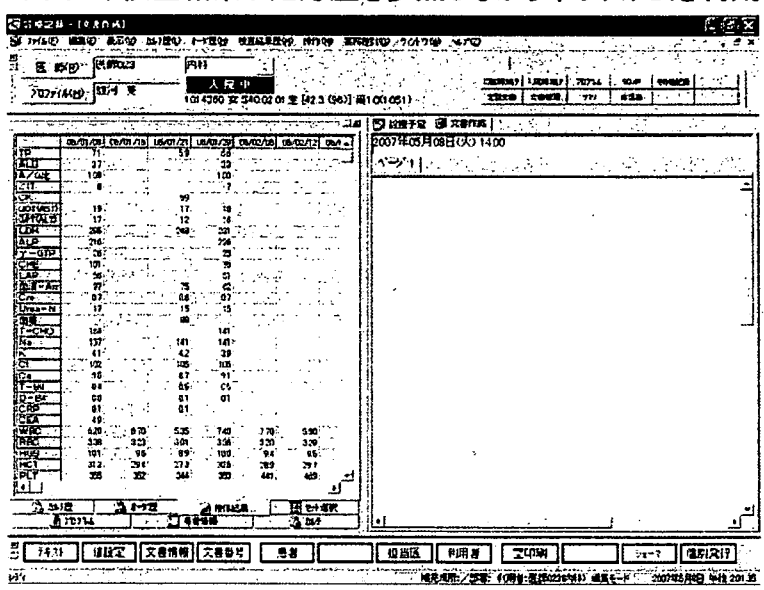
臨床研究支援ソリューション【CRF作成支援システムCR+】は、病院情報システムに
蓄積されている患者基本情報、検査結果情報、処方情報等の標準化された医療情報を
標準化されたデータ交換規約により、SS-MIXで開発された標準化ストレージを介して
CRF作成支援システムのデータベースに取り込むことができます。

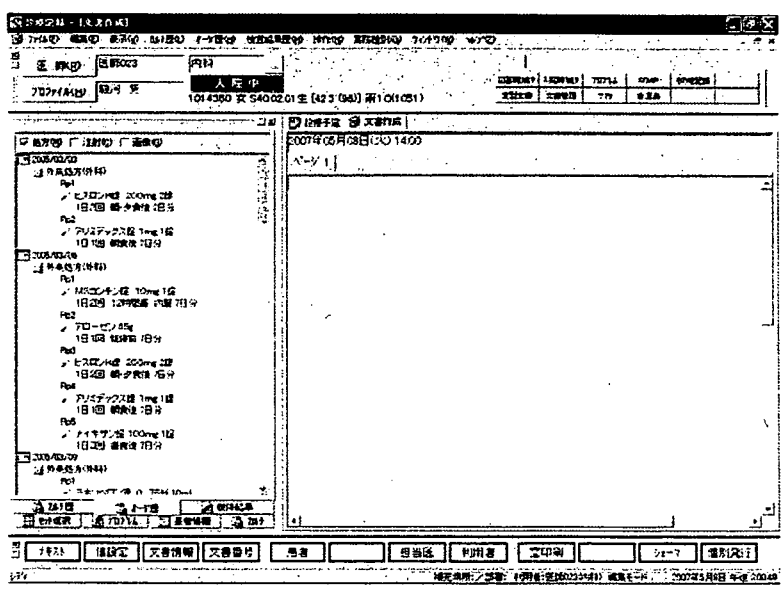
上記情報に加え、臨床研究ごとの書類提出等に必要な項目をテンプレート化して
入力することによって、CRFの作成を支援します。

■画面例と特長説明

・病院情報システムとの連携

SS-MIXで開発された標準化ストレージを介して既設の病院情報システムから取り込まれた医療情報を参照しながらCRFの作成を行います。
下図は、検査結果や処方歴を参照しながら本システムを利用する入力画面例です。

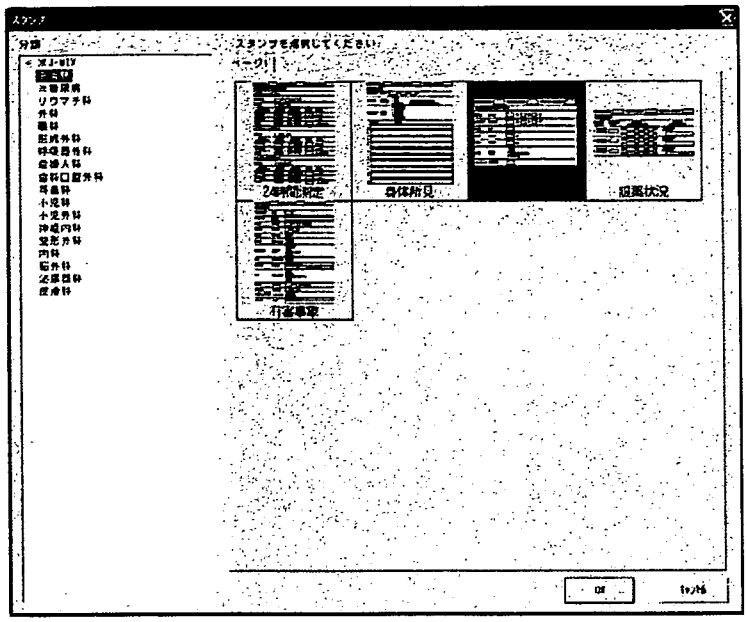




・スタンプ機能

本システムでは、記載が必要な項目をCRF毎にグループ化して登録したものを「スタンプ」と称し、CRF記載時に利用します。

下図は、治験用に登録されたスタンプの中から「人口統計学的データ」に関するスタンプを選択する画面例です。



・スタンプによる入力画面例

下図は、「人口統計学的データ」に関するスタンプをプログレスノートの入力画面に添付した入力画面例です。

スタンプが入力画面に展開されると、当該患者に関する既知の情報を入力する項目(当該患者の基本情報・検査結果値・等)には参照値が、また、再診時に繰り返し記載が必要な項目には、当該患者に対して記載された直近の内容が初期値として設定されます。