厚生労働省システム管理用データ項目属性一覧表

データ項目	表題	説明	フィールド長	フィールド値	ＤＴＤ記述子
J	ＭＨＬＷ管理項目	ヘッダ/エンティティ			**mhlwadminitemsicsr**
J.1	送信者ごとに固有の（症例）安全性報告識別子	安全性報告識別子	100AN		mhlwsafetyreportid
J.2	安全性報告バージョン番号	安全性報告バージョン番号	2AN		mhlwsafetyreportversion
J.3	本報告の最新情報入手日	ヘッダ/エンティティ			**mhlwadmicsrinfoobtndatesource**
J.3a	本報告の最新情報入手日	日付－書式	3N	102書式 CCYYMMDD	mhlwadmicsrreceiptdateformat
J.3b	本報告の最新情報入手日	日付－値	8N	CCYYMMDD	mhlwadmicsrreceiptdate
J.4	識別番号	ヘッダ/エンティティ			**mhlwadmicsrcasenum**
J.4a	識別番号（報告分類）	識別番号－報告分類	2N	1=A国内感染症症例報告(市販後) 2=B国内副作用症例報告(市販後) 3=C外国感染症症例報告(市販後) 4=D外国副作用症例報告(市販後) 5=E感染症研究報告(市販後) 6=F副作用研究報告(市販後) 7=G外国における製造等の中止、回収、廃棄等の措置報告(市販後) 8=H国内感染症症例報告(治験) 9=I 国内副作用症例報告(治験) 10=J外国感染症症例報告(治験) 11=K外国副作用症例報告(治験) 12=L感染症研究報告(治験) 13=M副作用研究報告(治験) 14=N外国における製造等の中止、回収、廃棄等の措置報告(治験) 15=O医薬部外品研究報告 16=P化粧品研究報告	mhlwadmicsrcasenumclass
J.4b	識別番号（番号）	識別番号－番号	8N		mhlwadmicsrcasenumb
J.5	機構報告回数	機構へ報告した回数（N回目）	2N		mhlwadmicsrmhlwcumreporttimes
J.6	完了、未完了区分		1N	1=未完了 2=完了	mhlwadmicsrcompleteclass
J.7	未完了に対するコメント		10000J		mhlwadmicsrcommentsincomplete
J.8	新医薬品等の区分（第１被疑薬）		1N	1=市販直後調査中 2=承認2年以内 3=未承認 4=一変治験中 5=該当なし	mhlwadmicsrnewdrugclass
J.9	今後の対応		10000J		mhlwadmicsrcountermeasures
J.10	その他参考事項等		10000J		mhlwadmicsrreporttimesevent
J.11	治験成分記号		70AN		mhlwcompoundnum
J.12	治験の概要	ヘッダ/エンティティ		以下は反復可能ブロック	**mhlwabstractofstudy**
J.12.i.1	対象疾患		1000J		mhlwindicationforstudy

データ項目	表題	説明	フィールド長	フィールド値	ＤＴＤ記述子
J.12.i.2	開発相		1N	1=第Ⅰ相 2=第Ⅱ相 3=第Ⅲ相 4=生物学的同等性試験 5=臨床薬理試験 6=申請準備中 7=申請中 8=その他	mhlwphaseofstudies
J.12.i.3	投薬中の症例の有無		1N	1=有 2=無	mhlwnumbofptundertreatment
J.13	備考	ヘッダ/エンティティ			**mhlwadmicsrremarks**
J.13.1	備考1		10000J		mhlwadmicsrremarks1
J.13.2	備考2		10000J		mhlwadmicsrremarks2
J.13.3	備考3		10000J		mhlwadmicsrremarks3
J.13.4	備考4		10000J		mhlwadmicsrremarks4

厚生労働省システム管理用データ項目DTD

```
<!DOCTYPE mhlwadminitemsicsr [
<!-- PUBLIC "-//ICHM2//DTD MHLW ADMIN 2.1//EN" "mhlw-admin2.1.dtd" -->


<!-- ================================================================ -->
<!-- Entities                                                  -->
<!-- ================================================================ -->

<!-- Use the lang attribute to indicate the language of an elements   --
  -- content via an ISO 639 language Code.                       -->

<!ENTITY % lang.att "lang CDATA #IMPLIED">

<!-- Standard Character Entities to escape SGML special characters.   --
  -- When "<", ">", and "&" occur in text, they should be replaced    --
  -- by "&lt;", "&gt;", and "&amp;" respectively.              -->

<!-- Less Than "<" -->
<!ENTITY lt    "&#60;">

<!-- Greater Than ">" -->
<!ENTITY gt    "&#62;">

<!-- Ampersand "&" -->
<!ENTITY amp    "&#38;">




<!-- ================================================================ -->
<!-- Elements and Attributes                                      -->
<!-- ================================================================ -->

<!ELEMENT mhlwadminitemsicsr         - -
 (mhlwsafetyreportid    ,
 mhlwsafetyreportversion? ,
 mhlwadmicsrinfoobtndatesource ,
 mhlwadmicsrcasenum     ,
 mhlwadmicsrmhlwcumreporttimes? ,
 mhlwadmicsrcompleteclass? ,
 mhlwadmicsrcommentsincomplete? ,
 mhlwadmicsrnewdrugclass?  ,
 mhlwadmicsrcountermeasures?  ,
 mhlwadmicsrreporttimesevent? ,
 mhlwcompoundnum?  ,
 mhlwabstractofstudy*  ,
 mhlwadmicsrremarks?)>
<!ATTLIST mhlwadminitemsicsr
 lang CDATA #REQUIRED
>


<!-- J.3 MHLW admin Date of receipt of the most recent information for this report -->
<!ELEMENT mhlwadmicsrinfoobtndatesource      - -
```

```
<!ELEMENT mhlwadmicsrinfoobtndatesource      － －
 (mhlwadmicsrreceiptdateformat   ,
 mhlwadmicsrreceiptdate)>
<!ATTLIST mhlwadmicsrinfoobtndatesource
 %lang.att;
>


<!-- J.4 MHLW admin icsr case number -->
<!ELEMENT mhlwadmicsrcasenum      － －
 (mhlwadmicsrcasenumclass?  ,
 mhlwadmicsrcasenumb?)>
<!ATTLIST mhlwadmicsrcasenum
 %lang.att;
>


<!-- J.12 MHLW admin icsr abstract of study -->
<!ELEMENT mhlwabstractofstudy      － －
 (mhlwindicationforstudy   ,
 mhlwphaseofstudies   ,
 mhlwnumbofptundertreatment)>
<!ATTLIST mhlwabstractofstudy
 %lang.att;
>


<!-- J.13 MHLW admin icsr remarks -->
<!ELEMENT mhlwadmicsrremarks      － －
 (mhlwadmicsrremarks1?   ,
 mhlwadmicsrremarks2?   ,
 mhlwadmicsrremarks3?   ,
 mhlwadmicsrremarks4?)>
<!ATTLIST mhlwadmicsrremarks
 %lang.att;
>


<!-- J.1  MHLW admin Safety Report Unique Identifier (ICSR A.1.0.1 same value) -->
<!-- A.1.0.1 Sender's(case) Safety Report Unique Identifier -->
<!ELEMENT mhlwsafetyreportid － － (#PCDATA)>
<!ATTLIST mhlwsafetyreportid
 %lang.att;
>


<!-- J.2 MHLW admin safety report version -->
<!ELEMENT mhlwsafetyreportversion － － (#PCDATA)>
<!ATTLIST mhlwsafetyreportversion
 %lang.att;
>


<!-- J.3a MHLW admin Date of receipt of the most recent information for this report -->
<!ELEMENT mhlwadmicsrreceiptdateformat － － (#PCDATA)>
<!ATTLIST mhlwadmicsrreceiptdateformat
 %lang.att:
```

```
  %lang.att;
>


<!-- J.3b MHLW admin Date of receipt of the most recent information for this report -->
<!ELEMENT mhlwadmicsrreceiptdate - - (#PCDATA) >
<!ATTLIST mhlwadmicsrreceiptdate
 %lang.att;
>


<!-- J.4a MHLW admin icsr case number class -->
<!ELEMENT mhlwadmicsrcasenumclass - - (#PCDATA) >
<!ATTLIST mhlwadmicsrcasenumclass
 %lang.att;
>


<!-- J.4b MHLW admin icsr case number -->
<!ELEMENT mhlwadmicsrcasenumb - - (#PCDATA) >
<!ATTLIST mhlwadmicsrcasenumb
 %lang.att;
>


<!-- J.5 MHLW admin icsr report the number of times -->
<!ELEMENT mhlwadmicsrmhlwcumreporttimes - - (#PCDATA) >
<!ATTLIST mhlwadmicsrmhlwcumreporttimes
 %lang.att;
>


<!-- J.6 MHLW admin icsr complete class -->
<!ELEMENT mhlwadmicsrcompleteclass - - (#PCDATA) >
<!ATTLIST mhlwadmicsrcompleteclass
 %lang.att;
>


<!-- J.7 MHLW admin icsr comments of complete -->
<!ELEMENT mhlwadmicsrcommentsincomplete - - (#PCDATA) >
<!ATTLIST mhlwadmicsrcommentsincomplete
 %lang.att;
>


<!-- J.8 MHLW admin icsr new drug class -->
<!ELEMENT mhlwadmicsrnewdrugclass - - (#PCDATA) >
<!ATTLIST mhlwadmicsrnewdrugclass
 %lang.att;
>


<!-- J.9 MHLW admin icsr counter measure -->
<!ELEMENT mhlwadmicsrcountermeasures - - (#PCDATA) >
<!ATTLIST mhlwadmicsrcountermeasures
```

```
<!ATTLIST mhlwadmicsrcountermeasures
 %lang.att;
>


<!-- J.10 MHLW admin icsr report times event -->
<!ELEMENT mhlwadmicsrreporttimesevent - - (#PCDATA) >
<!ATTLIST mhlwadmicsrreporttimesevent
 %lang.att;
>


<!-- J.11 MHLW admin icsr compound number -->
<!ELEMENT mhlwcompoundnum - - (#PCDATA) >
<!ATTLIST mhlwcompoundnum
 %lang.att;
>


<!-- J.12.i.1 MHLW admin icsr indication for study -->
<!ELEMENT mhlwindicationforstudy - - (#PCDATA) >
<!ATTLIST mhlwindicationforstudy
 %lang.att;
>


<!-- J.12.i.2 MHLW admin icsr phase of studies -->
<!ELEMENT mhlwphaseofstudies - - (#PCDATA) >
<!ATTLIST mhlwphaseofstudies
 %lang.att;
>


<!-- J.12.i.3 MHLW admin icsr number of pt under treatment -->
<!ELEMENT mhlwnumbofptundertreatment - - (#PCDATA) >
<!ATTLIST mhlwnumbofptundertreatment
 %lang.att;
>


<!-- J.13.1 MHLW admin icsr remarks1 -->
<!ELEMENT mhlwadmicsrremarks1 - - (#PCDATA) >
<!ATTLIST mhlwadmicsrremarks1
 %lang.att;
>


<!-- J.13.2 MHLW admin icsr remarks2 -->
<!ELEMENT mhlwadmicsrremarks2 - - (#PCDATA) >
<!ATTLIST mhlwadmicsrremarks2
 %lang.att;
>


<!-- J.13.3 MHLW admin icsr remarks3 -->
<!ELEMENT mhlwadmicsrremarks3 - - (#PCDATA) >
<!ATTLIST mhlwadmicsrremarks3
```

```
<!ATTLIST mhlwadmicsrremarks3
 %lang.att;
>



<!-- J.13.4 MHLW admin icsr remarks4 -->
<!ELEMENT mhlwadmicsrremarks4 - - (#PCDATA) >
<!ATTLIST mhlwadmicsrremarks4
 %lang.att;
>


]>
```