

Supplemental Update Report

CR Number: 2015054001 Implementation Date: 21-May-15 Related CR: 2015054001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT			
	<i>Subglottic laryngitis</i>	Approved After Suspension	Proposed PT	
HLT primary	<i>Upper respiratory tract infections</i>		<i>Subglottic laryngitis</i>	10076988
SOC primary	<i>Infections and infestations</i>		HLT primary	
			<i>Upper respiratory tract infections</i>	10046309
			SOC primary	
			<i>Infections and infestations</i>	10021881
			HLT secondary	
			<i>Upper respiratory tract infections</i>	10045573
			NEC	
			SOC secondary	
			<i>Respiratory, thoracic and mediastinal disorders</i>	10038738

MSSO Comment: The proposal to add a new PT Subglottic laryngitis to HLT Upper respiratory tract infections primary SOC Infections and infestations is approved as requested after suspension. Subglottic laryngitis is a recognized concept and will be secondarily linked to HLT Upper respiratory tract infections NEC.

CR Number: 2015054002 Implementation Date: 21-May-15 Related CR: 2015054002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT			
	<i>Chorditis vocalis inferior</i>	Approved After Suspension	Proposed LLT	
			<i>Chorditis vocalis inferior</i>	10076989 Current
			To PT	
			<i>Subglottic laryngitis</i>	10076988

MSSO Comment: The proposal to add a new LLT Chorditis vocalis inferior is approved as requested after suspension. Chorditis vocalis inferior will be added as a subconcept LLT under the new PT Subglottic laryngitis.

Supplemental Update Report

CR Number: 2015078932

Implementation Date: 20-May-15

Related CR: 2015078932

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Residual schizophrenia, unspecified state*

Approved as Requested

English term
*Residual schizophrenia,
unspecified state*

10038634 Current

Code# *10038634*

Code#
10038634

Language *German*

Language
German

Current translated term
*Residualschizophrenie,
unspezifischer Zustand*

Proposed new translation
*Residualschizophrenie, nicht
spezifizierter Zustand*

MSSO Comment: The proposal to rename the German translation of the term Residual schizophrenia, unspecified state (Code: 10038634) from Residualschizophrenie, unspezifischer Zustand to Residualschizophrenie, nicht spezifizierter Zustand is approved as requested.

Supplemental Update Report

CR Number: 2015078933

Implementation Date: 20-May-15

Related CR: 2015078933

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Schizo-affective type schizophrenia, unspecified state*
Code# 10039619
Language *German*

Approved as Requested

English term
Schizo-affective type schizophrenia, unspecified state
Code#
10039619
Language
German
Current translated term
schizoaffektive Form der Schizophrenie, unspezifischer Zustand
Proposed new translation
schizoaffektive Form der Schizophrenie, nicht spezifizierter Zustand

10039619 Current

MSSO The proposal to rename the German translation of the term Schizo-affective type schizophrenia, unspecified state (Code: 10039619) from schizoaffektive Form der Schizophrenie, unspezifischer Zustand to schizoaffektive Form der Schizophrenie, nicht spezifizierter Zustand is approved as requested.

Comment:

Supplemental Update Report

CR Number: 2015078934

Implementation Date: 20-May-15

Related CR: 2015078934

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Simple type schizophrenia, unspecified state*

Approved as Requested

English term

10040712 Current

Code# 10040712

*Simple type schizophrenia,
unspecified state*

Language *German*

Code#

10040712

Language

German

Current translated term

*einfache Form der
Schizophrenie, unspezifischer
Zustand*

Proposed new translation

*einfache Form der
Schizophrenie, nicht spezifizierter
Zustand*

MSSO Comment: The proposal to rename the German translation of the term Simple type schizophrenia, unspecified state (Code: 10040712) from einfache Form der Schizophrenie, unspezifischer Zustand to einfache Form der Schizophrenie, nicht spezifizierter Zustand is approved as requested.

Supplemental Update Report

CR Number: 2015078935

Implementation Date: 20-May-15

Related CR: 2015078935

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Spina bifida, without mention of hydrocephalus, unspecified region</i>	Approved as Requested	English term <i>Spina bifida, without mention of hydrocephalus, unspecified region</i>	10041535 Current
Code#	10041535		Code# 10041535	
Language	German		Language German	
			Current translated term <i>Spina bifida ohne Erwahnung eines Hydrozephalus, unspezifischer Bereich</i>	
			Proposed new translation <i>Spina bifida ohne Erwahnung eines Hydrozephalus, nicht spezifizierter Bereich</i>	

MSSO Comment: The proposal to rename the German translation of the term Spina bifida, without mention of hydrocephalus, unspecified region (Code: 10041535) from Spina bifida ohne Erwahnung eines Hydrozephalus, unspezifischer Bereich to Spina bifida ohne Erwahnung eines Hydrozephalus, nicht spezifizierter Bereich is approved as requested.

Supplemental Update Report

CR Number: 2015078936

Implementation Date: 20-May-15

Related CR: 2015078936

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Spondylosis of unspecified site</i>	Approved as Requested	English term	
Code#	10041682		<i>Spondylosis of unspecified site</i>	10041682 Current
Language	<i>German</i>		Code#	
			10041682	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Spondylose an unspezifischer Stelle</i>	
			Proposed new translation	
			<i>Spondylose an nicht spezifizierter Stelle</i>	

MSSO Comment: The proposal to rename the German translation of the term Spondylosis of unspecified site (Code: 10041682) from Spondylose an unspezifischer Stelle to Spondylose an nicht spezifizierter Stelle is approved as requested.

Supplemental Update Report

CR Number: 2015078937

Implementation Date: 20-May-15

Related CR: 2015078937

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Spondylosis of unspecified site without mention of myelopathy</i>	Approved as Requested	English term <i>Spondylosis of unspecified site without mention of myelopathy</i>	10041684 Current
Code#	10041684		Code# 10041684	
Language	German		Language German	
			Current translated term <i>Spondylose an unspezifischer Stelle ohne Erwaechnung von Myelopathie</i>	
			Proposed new translation <i>Spondylose an nicht spezifizierter Stelle ohne Erwaechnung von Myelopathie</i>	

MSSO Comment: The proposal to rename the German translation of the term Spondylosis of unspecified site without mention of myelopathy (Code: 10041684) from Spondylose an unspezifischer Stelle ohne Erwaechnung von Myelopathie to Spondylose an nicht spezifizierter Stelle ohne Erwaechnung von Myelopathie is approved as requested.

Supplemental Update Report

CR Number: 2015078938

Implementation Date: 20-May-15

Related CR: 2015078938

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Sternum sprain, unspecified part</i>	Approved as Requested	English term	
Code#	10042020		<i>Sternum sprain, unspecified part</i>	10042020 Current
Language	<i>German</i>		Code#	
			10042020	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Sternumverstauchung, unspezifischer Teil</i>	
			Proposed new translation	
			<i>Sternumverstauchung, nicht spezifizierter Teil</i>	

MSSO Comment: The proposal to rename the German translation of the term Sternum sprain, unspecified part (Code: 10042020) from Sternumverstauchung, unspezifischer Teil to Sternumverstauchung, nicht spezifizierter Teil is approved as requested.

Supplemental Update Report

CR Number: 2015078939

Implementation Date: 20-May-15

Related CR: 2015078939

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Superficial injuries of other, multiple, and unspecified sites*

Approved as Requested

English term
Superficial injuries of other, multiple, and unspecified sites

10042526 Current

Code# 10042526

Language *German*

Code#
10042526

Language
German

Current translated term
oberflaechliche Verletzungen sonstiger mehrfacher und unspezifischer Stellen

Proposed new translation
oberflaechliche Verletzungen sonstiger mehrfacher und nicht spezifizierter Stellen

MSSO Comment: The proposal to rename the German translation of the term Superficial injuries of other, multiple, and unspecified sites (Code: 10042526) from oberflaechliche Verletzungen sonstiger mehrfacher und unspezifischer Stellen to oberflaechliche Verletzungen sonstiger mehrfacher und nicht spezifizierter Stellen is approved as requested.

Supplemental Update Report

CR Number: 2015078940

Implementation Date: 20-May-15

Related CR: 2015078940

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Toxic effect of unspecified lead compound*

Approved as Requested

English term

Code# 10044215

Toxic effect of unspecified lead compound

10044215 Current

Language *German*

Code#

10044215

Language

German

Current translated term

toxischer Effekt unspezifischer Bleiverbindungen

Proposed new translation

toxischer Effekt nicht spezifizierter Bleiverbindungen

MSSO Comment: The proposal to rename the German translation of the term Toxic effect of unspecified lead compound (Code: 10044215) from toxischer Effekt unspezifischer Bleiverbindungen to toxischer Effekt nicht spezifizierter Bleiverbindungen is approved as requested.

CR Number: 2015078941

Implementation Date: 20-May-15

Related CR: 2015078941

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Toxic nodular goiter, unspecified type*

Approved as Requested

English term

Code# 10044239

Toxic nodular goiter, unspecified type

10044239 Current

Language *German*

Code#

10044239

Language

German

Current translated term

toxische nodulaere Struma, unspezifischer Typ

Proposed new translation

toxische nodulaere Struma, nicht spezifizierter Typ

MSSO Comment: The proposal to rename the German translation of the term Toxic nodular goiter, unspecified type (Code: 10044239) from toxische nodulaere Struma, unspezifischer Typ to toxische nodulaere Struma, nicht spezifizierter Typ is approved as requested.

Supplemental Update Report

CR Number: 2015078942

Implementation Date: 20-May-15

Related CR: 2015078942

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Toxic nodular goitre, unspecified type</i>	Approved as Requested	English term	10044244 Current
Code#	10044244		<i>Toxic nodular goitre, unspecified type</i>	
Language	German		Code#	
			10044244	
			Language	
			German	
			Current translated term	
			<i>toxische nodulaere Struma, unspezifischer Typ</i>	
			Proposed new translation	
			<i>toxische nodulaere Struma, nicht spezifizierter Typ</i>	

MSSO Comment: The proposal to rename the German translation of the term Toxic nodular goitre, unspecified type (Code: 10044244) from toxische nodulaere Struma, unspezifischer Typ to toxische nodulaere Struma, nicht spezifizierter Typ is approved as requested.

Supplemental Update Report

CR Number: 2015078943

Implementation Date: 20-May-15

Related CR: 2015078943

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Trans-sexualism with unspecified sexual history* Approved as Requested
Code# 10044341
Language *German*

English term
Trans-sexualism with unspecified sexual history 10044341 Current
Code#
10044341
Language
German
Current translated term
Transsexualitaet mit unspezifischer sexueller Vorgeschichte
Proposed new translation
Transsexualitaet mit nicht spezifizierter sexueller Vorgeschichte

MSSO The proposal to rename the German translation of the term Trans-sexualism with unspecified sexual history (Code: 10044341) from Transsexualitaet mit unspezifischer
Comment: sexueller Vorgeschichte to Transsexualitaet mit nicht spezifizierter sexueller Vorgeschichte is approved as requested.

Supplemental Update Report

CR Number: 2015078944 Implementation Date: 20-May-15 Related CR: 2015078944

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>With hydrocephalus, spina bifida, unspecified region</i>	Approved as Requested	English term <i>With hydrocephalus, spina bifida, unspecified region</i>	10047996 Current
Code#	10047996		Code# 10047996	
Language	German		Language German Current translated term <i>mit Hydrozephalus, Spina bifida, unspezifischer Bereich</i> Proposed new translation <i>mit Hydrozephalus, Spina bifida, nicht spezifizierter Bereich</i>	

MSSO Comment: The proposal to rename the German translation of the term With hydrocephalus, spina bifida, unspecified region (Code: 10047996) from mit Hydrozephalus, Spina bifida, unspezifischer Bereich to mit Hydrozephalus, Spina bifida, nicht spezifizierter Bereich is approved as requested.

CR Number: 2015078945 Implementation Date: 20-May-15 Related CR: 2015078945

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Burn of face, unspecified degree</i>	Approved as Requested	English term <i>Burn of face, unspecified degree</i>	10054963 Current
Code#	10054963		Code# 10054963	
Language	German		Language German Current translated term <i>Verbrennung des Gesichts, unspezifischer Grad</i> Proposed new translation <i>Verbrennung des Gesichts, nicht spezifizierter Grad</i>	

MSSO Comment: The proposal to rename the German translation of the term Burn of face, unspecified degree (Code: 10054963) from Verbrennung des Gesichts, unspezifischer Grad to Verbrennung des Gesichts, nicht spezifizierter Grad is approved as requested.

Supplemental Update Report

CR Number: 2015078946

Implementation Date: 20-May-15

Related CR: 2015078946

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Haemangioma of unspecified site*

Approved as Requested

English term

Haemangioma of unspecified site

10055903 Current

Code# 10055903

Code#
10055903

Language *German*

Language
German

Current translated term
*Haemangiom an unspezifischer
Stelle*

Proposed new translation
*Haemangiom an nicht
spezifizierter Stelle*

MSSO Comment: The proposal to rename the German translation of the term Haemangioma of unspecified site (Code: 10055903) from Haemangiom an unspezifischer Stelle to Haemangiom an nicht spezifizierter Stelle is approved as requested.

CR Number: 2015078947

Implementation Date: 20-May-15

Related CR: 2015078947

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Prolonged labour, unspecified type, antepartum*

Approved as Requested

English term

*Prolonged labour, unspecified
type, antepartum*

10056162 Current

Code# 10056162

Code#
10056162

Language *German*

Language
German

Current translated term
*langandauernde Wehen,
unspezifischer Typ, antepartal*

Proposed new translation
*langandauernde Wehen, nicht
spezifizierter Typ, antepartal*

MSSO Comment: The proposal to rename the German translation of the term Prolonged labour, unspecified type, antepartum (Code: 10056162) from langandauernde Wehen, unspezifischer Typ, antepartal to langandauernde Wehen, nicht spezifizierter Typ, antepartal is approved as requested.

Supplemental Update Report

CR Number: 2015078948

Implementation Date: 20-May-15

Related CR: 2015078948

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Prolonged labour, unspecified type, delivered</i>	Approved as Requested	English term	
Code#	10056163		<i>Prolonged labour, unspecified type, delivered</i>	10056163 Current
Language	<i>German</i>		Code#	
			10056163	
			Language	
			<i>German</i>	
			Current translated term	
			<i>langandauernde Wehen, unspezifischer Typ, entbunden</i>	
			Proposed new translation	
			<i>langandauernde Wehen, nicht spezifizierter Typ, entbunden</i>	

MSSO Comment: The proposal to rename the German translation of the term Prolonged labour, unspecified type, delivered (Code: 10056163) from langandauernde Wehen, unspezifischer Typ, entbunden to langandauernde Wehen, nicht spezifizierter Typ, entbunden is approved as requested.

Supplemental Update Report

CR Number: 2015078949

Implementation Date: 20-May-15

Related CR: 2015078949

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Prolonged labour, unspecified type, unspecified as to episode of care* Approved as Requested
Code# 10056164
Language *German*

English term *Prolonged labour, unspecified type, unspecified as to episode of care* 10056164 Current
Code# 10056164
Language *German*
Current translated term *langandauernde Wehen, unspezifischer Typ, ohne Angabe der Behandlungsepisode*
Proposed new translation *langandauernde Wehen, nicht spezifizierter Typ, ohne Angabe der Behandlungsepisode*

MSSO Comment: The proposal to rename the German translation of the term Prolonged labour, unspecified type, unspecified as to episode of care (Code: 10056164) from langandauernde Wehen, unspezifischer Typ, ohne Angabe der Behandlungsepisode to langandauernde Wehen, nicht spezifizierter Typ, ohne Angabe der Behandlungsepisode is approved as requested.

Supplemental Update Report

CR Number: 2015078950	Implementation Date: 20-May-15	Related CR: 2015078950	MedDRA Code #	
Change Requested	Rename Translated Term	Final Disposition	Final Placement	
English term	<i>Burn of upper limb, excl wrist and hand, unspecified degree</i>	Approved as Requested	English term <i>Burn of upper limb, excl wrist and hand, unspecified degree</i>	10056786 Current
Code#	10056786		Code# 10056786	
Language	German		Language German	
			Current translated term <i>Verbrennung einer oberen Gliedmasse, ausschl Handgelenk und Hand, unspezifischer Grad</i>	
			Proposed new translation <i>Verbrennung einer oberen Gliedmasse, ausschl Handgelenk und Hand, nicht spezifizierter Grad</i>	

MSSO Comment: The proposal to rename the German translation of the term Burn of upper limb, excl wrist and hand, unspecified degree (Code: 10056786) from *Verbrennung einer oberen Gliedmasse, ausschl Handgelenk und Hand, unspezifischer Grad* to *Verbrennung einer oberen Gliedmasse, ausschl Handgelenk und Hand, nicht spezifizierter Grad* is approved as requested.

CR Number: 2015078951	Implementation Date: 20-May-15	Related CR: 2015078951	MedDRA Code #	
Change Requested	Rename Translated Term	Final Disposition	Final Placement	
English term	<i>Unspecified abortion</i>	Approved as Requested	English term <i>Unspecified abortion</i>	10045581 Current
Code#	10045581		Code# 10045581	
Language	German		Language German	
			Current translated term <i>unspezifischer Abort</i>	
			Proposed new translation <i>nicht spezifizierter Abort</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified abortion (Code: 10045581) from *unspezifischer Abort* to *nicht spezifizierter Abort* is approved as requested.

Supplemental Update Report

CR Number: 2015078952

Implementation Date: 20-May-15

Related CR: 2015078952

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified cataract*

Approved as Requested

English term
Unspecified cataract

10045649 Current

Code# *10045649*

Code#
10045649

Language *German*

Language
German

Current translated term
unspezifischer Katarakt

Proposed new translation
nicht spezifizierter Katarakt

MSSO Comment: The proposal to rename the German translation of the term Unspecified cataract (Code: 10045649) from unspezifischer Katarakt to nicht spezifizierter Katarakt is approved as requested.

CR Number: 2015078953

Implementation Date: 20-May-15

Related CR: 2015078953

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified chest pain*

Approved as Requested

English term
Unspecified chest pain

10045653 Current

Code# *10045653*

Code#
10045653

Language *German*

Language
German

Current translated term
unspezifischer Brustschmerz

Proposed new translation
nicht spezifizierter Brustschmerz

MSSO Comment: The proposal to rename the German translation of the term Unspecified chest pain (Code: 10045653) from unspezifischer Brustschmerz to nicht spezifizierter Brustschmerz is approved as requested.

Supplemental Update Report

CR Number: 2015078954 Implementation Date: 20-May-15 Related CR: 2015078954

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified fracture of ankle, closed</i>	Approved as Requested	English term	10045876 Current
Code#	10045876		<i>Unspecified fracture of ankle, closed</i>	
Language	German		Code#	
			10045876	
			Language	
			German	
			Current translated term	
			<i>unspezifischer Bruch des Knochels, geschlossen</i>	
			Proposed new translation	
			<i>nicht spezifizierter Bruch des Knochels, geschlossen</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified fracture of ankle, closed (Code: 10045876) from unspezifischer Bruch des Knochels, geschlossen to nicht spezifizierter Bruch des Knochels, geschlossen is approved as requested.

CR Number: 2015078955 Implementation Date: 20-May-15 Related CR: 2015078955

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified fracture of ankle, open</i>	Approved as Requested	English term	10045877 Current
Code#	10045877		<i>Unspecified fracture of ankle, open</i>	
Language	German		Code#	
			10045877	
			Language	
			German	
			Current translated term	
			<i>unspezifischer Bruch des Knochels, offen</i>	
			Proposed new translation	
			<i>nicht spezifizierter Bruch des Knochels, offen</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified fracture of ankle, open (Code: 10045877) from unspezifischer Bruch des Knochels, offen to nicht spezifizierter Bruch des Knochels, offen is approved as requested.

Supplemental Update Report

CR Number: 2015078956 Implementation Date: 20-May-15 Related CR: 2015078956

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified genital prolapse</i>	Approved as Requested	English term	10045885 Current
Code#	10045885		<i>Unspecified genital prolapse</i>	
Language	<i>German</i>		Code#	
			10045885	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer Prolaps der Geschlechtsorgane</i>	
			Proposed new translation	
			<i>nicht spezifizierter Prolaps der Geschlechtsorgane</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified genital prolapse (Code: 10045885) from unspezifischer Prolaps der Geschlechtsorgane to nicht spezifizierter Prolaps der Geschlechtsorgane is approved as requested.

CR Number: 2015078957 Implementation Date: 20-May-15 Related CR: 2015078957

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified hearing loss</i>	Approved as Requested	English term	10045900 Current
Code#	10045900		<i>Unspecified hearing loss</i>	
Language	<i>German</i>		Code#	
			10045900	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer Hoerverlust</i>	
			Proposed new translation	
			<i>nicht spezifizierter Hoerverlust</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified hearing loss (Code: 10045900) from unspezifischer Hoerverlust to nicht spezifizierter Hoerverlust is approved as requested.

Supplemental Update Report

CR Number: 2015078958

Implementation Date: 20-May-15

Related CR: 2015078958

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified immunity deficiency*

Approved as Requested

English term

Unspecified immunity deficiency

10045922 Current

Code# 10045922

Code#

10045922

Language *German*

Language

German

Current translated term

unspezifischer Immunmangel

Proposed new translation

nicht spezifizierter Immunmangel

MSSO Comment: The proposal to rename the German translation of the term Unspecified immunity deficiency (Code: 10045922) from unspezifischer Immunmangel to nicht spezifizierter Immunmangel is approved as requested.

CR Number: 2015078959

Implementation Date: 20-May-15

Related CR: 2015078959

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified nasal polyp*

Approved as Requested

English term

Unspecified nasal polyp

10046043 Current

Code# 10046043

Code#

10046043

Language *German*

Language

German

Current translated term

unspezifischer Polyp der Nase

Proposed new translation

nicht spezifizierter Polyp der Nase

MSSO Comment: The proposal to rename the German translation of the term Unspecified nasal polyp (Code: 10046043) from unspezifischer Polyp der Nase to nicht spezifizierter Polyp der Nase is approved as requested.

Supplemental Update Report

CR Number: 2015078960 Implementation Date: 20-May-15 Related CR: 2015078960

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified nutritional deficiency</i>	Approved as Requested	English term	10046058 Current
Code#	10046058		<i>Unspecified nutritional deficiency</i>	
Language	<i>German</i>		Code#	
			10046058	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer</i>	
			<i>Ernaehrungsmangel</i>	
			Proposed new translation	
			<i>nicht spezifizierter</i>	
			<i>Ernaehrungsmangel</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified nutritional deficiency (Code: 10046058) from unspezifischer Ernaehrungsmangel to nicht spezifizierter Ernaehrungsmangel is approved as requested.

CR Number: 2015078961 Implementation Date: 20-May-15 Related CR: 2015078961

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified paranoid state</i>	Approved as Requested	English term	10046090 Current
Code#	10046090		<i>Unspecified paranoid state</i>	
Language	<i>German</i>		Code#	
			10046090	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer paranoider</i>	
			<i>Zustand</i>	
			Proposed new translation	
			<i>nicht spezifizierter paranoider</i>	
			<i>Zustand</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified paranoid state (Code: 10046090) from unspezifischer paranoider Zustand to nicht spezifizierter paranoider Zustand is approved as requested.

Supplemental Update Report

CR Number: 2015078962	Implementation Date: 20-May-15	Related CR: 2015078962		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified perineal laceration during delivery</i>	Approved as Requested	English term	
Code#	10046092		<i>Unspecified perineal laceration during delivery</i>	10046092 Current
Language	<i>German</i>		Code#	
			10046092	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer Dammriss waehrend der Entbindung</i>	
			Proposed new translation	
			<i>nicht spezifizierter Dammriss waehrend der Entbindung</i>	
MSSO Comment:	The proposal to rename the German translation of the term Unspecified perineal laceration during delivery (Code: 10046092) from unspezifischer Dammriss waehrend der Entbindung to nicht spezifizierter Dammriss waehrend der Entbindung is approved as requested.			

CR Number: 2015078963	Implementation Date: 20-May-15	Related CR: 2015078963		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified pleural effusion</i>	Approved as Requested	English term	
Code#	10046099		<i>Unspecified pleural effusion</i>	10046099 Current
Language	<i>German</i>		Code#	
			10046099	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer Pleuraerguss</i>	
			Proposed new translation	
			<i>nicht spezifizierter Pleuraerguss</i>	
MSSO Comment:	The proposal to rename the German translation of the term Unspecified pleural effusion (Code: 10046099) from unspezifischer Pleuraerguss to nicht spezifizierter Pleuraerguss is approved as requested.			

Supplemental Update Report

CR Number: 2015078964 Implementation Date: 20-May-15 Related CR: 2015078964

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified reduction deformity of upper limb, congenital</i>	Approved as Requested	English term <i>Unspecified reduction deformity of upper limb, congenital</i>	10046133 Current
Code#	10046133		Code# 10046133	
Language	German		Language German Current translated term <i>unspezifischer Reduktionsdefekt der oberen Gliedmassen, kongenital</i> Proposed new translation <i>nicht spezifizierter Reduktionsdefekt der oberen Gliedmassen, kongenital</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified reduction deformity of upper limb, congenital (Code: 10046133) from unspezifischer Reduktionsdefekt der oberen Gliedmassen, kongenital to nicht spezifizierter Reduktionsdefekt der oberen Gliedmassen, kongenital is approved as requested.

CR Number: 2015078965 Implementation Date: 20-May-15 Related CR: 2015078965

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified visual loss</i>	Approved as Requested	English term <i>Unspecified visual loss</i>	10046239 Current
Code#	10046239		Code# 10046239	
Language	German		Language German Current translated term <i>unspezifischer Sehverlust</i> Proposed new translation <i>nicht spezifizierter Sehverlust</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified visual loss (Code: 10046239) from unspezifischer Sehverlust to nicht spezifizierter Sehverlust is approved as requested.

Supplemental Update Report

CR Number: 2015078966	Implementation Date: 20-May-15	Related CR: 2015078966		MedDRA Code #
Change Requested	Rename Translated Term	Final Disposition	Final Placement	
English term	<i>Unspecified vitamin A deficiency</i>	Approved as Requested	English term	
Code#	10046240		<i>Unspecified vitamin A deficiency</i>	10046240 Current
Language	<i>German</i>		Code#	
			10046240	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer Vitamin A-Mangel</i>	
			Proposed new translation	
			<i>nicht spezifizierter Vitamin A-Mangel</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified vitamin A deficiency (Code: 10046240) from unspezifischer Vitamin A-Mangel to nicht spezifizierter Vitamin A-Mangel is approved as requested.

CR Number: 2015078967	Implementation Date: 20-May-15	Related CR: 2015078967		MedDRA Code #
Change Requested	Rename Translated Term	Final Disposition	Final Placement	
English term	<i>Unspecified vitamin B deficiency</i>	Approved as Requested	English term	
Code#	10046241		<i>Unspecified vitamin B deficiency</i>	10046241 Current
Language	<i>German</i>		Code#	
			10046241	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer Vitamin B-Mangel</i>	
			Proposed new translation	
			<i>nicht spezifizierter Vitamin B-Mangel</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified vitamin B deficiency (Code: 10046241) from unspezifischer Vitamin B-Mangel to nicht spezifizierter Vitamin B-Mangel is approved as requested.

Supplemental Update Report

CR Number: 2015078968	Implementation Date: 20-May-15	Related CR: 2015078968		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified vitamin D deficiency</i>	Approved as Requested	English term	
Code#	10046242		<i>Unspecified vitamin D deficiency</i>	10046242 Current
Language	<i>German</i>		Code#	
			10046242	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer Vitamin D-Mangel</i>	
			Proposed new translation	
			<i>nicht spezifizierter Vitamin D-Mangel</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified vitamin D deficiency (Code: 10046242) from unspezifischer Vitamin D-Mangel to nicht spezifizierter Vitamin D-Mangel is approved as requested.

CR Number: 2015078969	Implementation Date: 20-May-15	Related CR: 2015078969		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified vitamin deficiency</i>	Approved as Requested	English term	
Code#	10046243		<i>Unspecified vitamin deficiency</i>	10046243 Current
Language	<i>German</i>		Code#	
			10046243	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifischer Vitaminmangel</i>	
			Proposed new translation	
			<i>nicht spezifizierter Vitaminmangel</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified vitamin deficiency (Code: 10046243) from unspezifischer Vitaminmangel to nicht spezifizierter Vitaminmangel is approved as requested.

Supplemental Update Report

CR Number: 2015078970

Implementation Date: 20-May-15

Related CR: 2015078970

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology aggressive recurrent</i>	Approved as Requested	English term <i>Non-Hodgkin's lymphoma unspecified histology aggressive recurrent</i>	10029609
Code#	10029609		Code# 10029609	
Language	German		Language German	
			Current translated term <i>Non-Hodgkin-Lymphome mit unspezifischer Histologie aggressiv Rezidiv</i>	
			Proposed new translation <i>Non-Hodgkin-Lymphome mit nicht spezifizierter Histologie aggressiv Rezidiv</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology aggressive recurrent (Code: 10029609) from Non-Hodgkin-Lymphome mit unspezifischer Histologie aggressiv Rezidiv to Non-Hodgkin-Lymphome mit nicht spezifizierter Histologie aggressiv Rezidiv is approved as requested.

Supplemental Update Report

CR Number: 2015078971

Implementation Date: 20-May-15

Related CR: 2015078971

<u>Change Requested</u>	<u>Rename Translated Term</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology aggressive refractory</i>	Approved as Requested	English term	10029610
Code#	10029610		<i>Non-Hodgkin's lymphoma unspecified histology aggressive refractory</i>	
Language	German		Code#	
			10029610	
			Language	
			German	
			Current translated term	
			<i>Non-Hodgkin-Lymphome mit unspezifischer Histologie aggressiv refraktaer</i>	
			Proposed new translation	
			<i>Non-Hodgkin-Lymphome mit nicht spezifizierter Histologie aggressiv refraktaer</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology aggressive refractory (Code: 10029610) from Non-Hodgkin-Lymphome mit unspezifischer Histologie aggressiv refraktaer to Non-Hodgkin-Lymphome mit nicht spezifizierter Histologie aggressiv refraktaer is approved as requested.

Supplemental Update Report

CR Number: 2015078972

Implementation Date: 20-May-15

Related CR: 2015078972

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology aggressive stage I</i>	Approved as Requested	English term <i>Non-Hodgkin's lymphoma unspecified histology aggressive stage I</i>	10029611
Code#	10029611		Code# 10029611	
Language	German		Language German	
			Current translated term <i>Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv Stadium I</i>	
			Proposed new translation <i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv Stadium I</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology aggressive stage I (Code: 10029611) from Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv Stadium I to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv Stadium I is approved as requested.

Supplemental Update Report

CR Number: 2015078973

Implementation Date: 20-May-15

Related CR: 2015078973

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology aggressive stage II</i>	Approved as Requested	English term <i>Non-Hodgkin's lymphoma unspecified histology aggressive stage II</i>	10029612
Code#	10029612		Code# 10029612	
Language	German		Language German	
			Current translated term <i>Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv Stadium II</i>	
			Proposed new translation <i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv Stadium II</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology aggressive stage II (Code: 10029612) from Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv Stadium II to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv Stadium II is approved as requested.

Supplemental Update Report

CR Number: 2015078974

Implementation Date: 20-May-15

Related CR: 2015078974

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology aggressive stage III</i>	Approved as Requested	English term	
Code#	10029613		<i>Non-Hodgkin's lymphoma unspecified histology aggressive stage III</i>	10029613
Language	<i>German</i>		Code#	
			10029613	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv Stadium III</i>	
			Proposed new translation	
			<i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv Stadium III</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology aggressive stage III (Code: 10029613) from Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv Stadium III to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv Stadium III is approved as requested.

Supplemental Update Report

CR Number: 2015078975

Implementation Date: 20-May-15

Related CR: 2015078975

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology aggressive stage IV</i>	Approved as Requested	English term	10029614
Code#	10029614		<i>Non-Hodgkin's lymphoma unspecified histology aggressive stage IV</i>	
Language	German		Code#	
			10029614	
			Language	
			German	
			Current translated term	
			<i>Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv Stadium IV</i>	
			Proposed new translation	
			<i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv Stadium IV</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology aggressive stage IV (Code: 10029614) from Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv Stadium IV to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv Stadium IV is approved as requested.

Supplemental Update Report

CR Number: 2015078976

Implementation Date: 20-May-15

Related CR: 2015078976

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology indolent stage I</i>	Approved as Requested	English term <i>Non-Hodgkin's lymphoma unspecified histology indolent stage I</i>	10029622
Code#	10029622		Code# 10029622	
Language	German		Language German	
			Current translated term <i>Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent Stadium I</i>	
			Proposed new translation <i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent Stadium I</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology indolent stage I (Code: 10029622) from Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent Stadium I to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent Stadium I is approved as requested.

Supplemental Update Report

CR Number: 2015078977

Implementation Date: 20-May-15

Related CR: 2015078977

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology indolent stage II</i>	Approved as Requested	English term	10029623
Code#	10029623		<i>Non-Hodgkin's lymphoma unspecified histology indolent stage II</i>	
Language	<i>German</i>		Code#	
			10029623	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent Stadium II</i>	
			Proposed new translation	
			<i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent Stadium II</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology indolent stage II (Code: 10029623) from Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent Stadium II to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent Stadium II is approved as requested.

Supplemental Update Report

CR Number: 2015078978

Implementation Date: 20-May-15

Related CR: 2015078978

<u>Change Requested</u>	<u>Rename Translated Term</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology indolent stage III</i>	Approved as Requested	English term	10029624
Code#	10029624		<i>Non-Hodgkin's lymphoma unspecified histology indolent stage III</i>	
Language	German		Code#	
			10029624	
			Language	
			German	
			Current translated term	
			<i>Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent Stadium III</i>	
			Proposed new translation	
			<i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent Stadium III</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology indolent stage III (Code: 10029624) from Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent Stadium III to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent Stadium III is approved as requested.

Supplemental Update Report

CR Number: 2015078979

Implementation Date: 20-May-15

Related CR: 2015078979

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology indolent stage IV</i>	Approved as Requested	English term	10029625
Code#	10029625		<i>Non-Hodgkin's lymphoma unspecified histology indolent stage IV</i>	
Language	<i>German</i>		Code#	
			10029625	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent Stadium IV</i>	
			Proposed new translation	
			<i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent Stadium IV</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology indolent stage IV (Code: 10029625) from Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent Stadium IV to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent Stadium IV is approved as requested.

Supplemental Update Report

CR Number: 2015078980	Implementation Date: 20-May-15	Related CR: 2015078980		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Neoplasm of cornea unspecified malignancy</i>	Approved as Requested	English term	
Code#	10052903		<i>Neoplasm of cornea unspecified malignancy</i>	10052903
Language	German		Code#	
			10052903	
			Language	
			German	
			Current translated term	
			<i>Neubildungen der Hornhaut unspezifischer Malignitaet</i>	
			Proposed new translation	
			<i>Neubildungen der Hornhaut nicht spezifizierter Malignitaet</i>	

MSSO Comment: The proposal to rename the German translation of the term Neoplasm of cornea unspecified malignancy (Code: 10052903) from Neubildungen der Hornhaut unspezifischer Malignitaet to Neubildungen der Hornhaut nicht spezifizierter Malignitaet is approved as requested.

CR Number: 2015078981	Implementation Date: 20-May-15	Related CR: 2015078981		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Splenic neoplasm malignancy unspecified</i>	Approved as Requested	English term	
Code#	10053190		<i>Splenic neoplasm malignancy unspecified</i>	10053190
Language	German		Code#	
			10053190	
			Language	
			German	
			Current translated term	
			<i>Neubildung der Milz unspezifischer Malignitaet</i>	
			Proposed new translation	
			<i>Neubildung der Milz nicht spezifizierter Malignitaet</i>	

MSSO Comment: The proposal to rename the German translation of the term Splenic neoplasm malignancy unspecified (Code: 10053190) from Neubildung der Milz unspezifischer Malignitaet to Neubildung der Milz nicht spezifizierter Malignitaet is approved as requested.

Supplemental Update Report

CR Number: 2015078982	Implementation Date: 20-May-15	Related CR: 2015078982		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology aggressive</i>	Approved as Requested	English term <i>Non-Hodgkin's lymphoma unspecified histology aggressive</i>	10063908
Code#	10063908		Code# 10063908	
Language	German		Language German	
			Current translated term <i>Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv</i>	
			Proposed new translation <i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology aggressive (Code: 10063908) from Non-Hodgkin-Lymphom mit unspezifischer Histologie aggressiv to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie aggressiv is approved as requested.

CR Number: 2015078983	Implementation Date: 20-May-15	Related CR: 2015078983		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Non-Hodgkin's lymphoma unspecified histology indolent</i>	Approved as Requested	English term <i>Non-Hodgkin's lymphoma unspecified histology indolent</i>	10065856
Code#	10065856		Code# 10065856	
Language	German		Language German	
			Current translated term <i>Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent</i>	
			Proposed new translation <i>Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent</i>	

MSSO Comment: The proposal to rename the German translation of the term Non-Hodgkin's lymphoma unspecified histology indolent (Code: 10065856) from Non-Hodgkin-Lymphom mit unspezifischer Histologie indolent to Non-Hodgkin-Lymphom mit nicht spezifizierter Histologie indolent is approved as requested.

Supplemental Update Report

CR Number: 2015078984	Implementation Date: 20-May-15	Related CR: 2015078984		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Tumours of unspecified malignancy (SMQ)</i>	Approved as Requested	English term	
Code#	20000195		<i>Tumours of unspecified malignancy (SMQ)</i>	20000195
Language	<i>German</i>		Code#	
			20000195	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Tumoren unspezifischer Malignitaet (SMQ)</i>	
			Proposed new translation	
			<i>Tumoren nicht spezifizierter Malignitaet (SMQ)</i>	
MSSO	The proposal to rename the German translation of the term Tumours of unspecified malignancy (SMQ) (Code: 20000195) from Tumoren unspezifischer Malignitaet (SMQ)			
Comment:	to Tumoren nicht spezifizierter Malignitaet (SMQ) is approved as requested.			

CR Number: 2015078985	Implementation Date: 20-May-15	Related CR: 2015078985		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Biliary tumours of unspecified malignancy (SMQ)</i>	Approved as Requested	English term	
Code#	20000197		<i>Biliary tumours of unspecified malignancy (SMQ)</i>	20000197
Language	<i>German</i>		Code#	
			20000197	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Tumoren des Gallensystems unspezifischer Malignitaet (SMQ)</i>	
			Proposed new translation	
			<i>Tumoren des Gallensystems nicht spezifizierter Malignitaet (SMQ)</i>	
MSSO	The proposal to rename the German translation of the term Biliary tumours of unspecified malignancy (SMQ) (Code: 20000197) from Tumoren des Gallensystems			
Comment:	unspezifischer Malignitaet (SMQ) to Tumoren des Gallensystems nicht spezifizierter Malignitaet (SMQ) is approved as requested.			

Supplemental Update Report

CR Number: 2015078986

Implementation Date: 20-May-15

Related CR: 2015078986

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Breast tumours of unspecified malignancy (SMQ)</i>	Approved as Requested	English term	
Code#	20000199		<i>Breast tumours of unspecified malignancy (SMQ)</i>	20000199
Language	German		Code#	
			20000199	
			Language	
			German	
			Current translated term	
			<i>Tumoren der Brust unspezifischer Malignitaet (SMQ)</i>	
			Proposed new translation	
			<i>Tumoren der Brust nicht spezifizierter Malignitaet (SMQ)</i>	

MSSO Comment: The proposal to rename the German translation of the term Breast tumours of unspecified malignancy (SMQ) (Code: 20000199) from Tumoren der Brust unspezifischer Malignitaet (SMQ) to Tumoren der Brust nicht spezifizierter Malignitaet (SMQ) is approved as requested.

CR Number: 2015078987

Implementation Date: 20-May-15

Related CR: 2015078987

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Ovarian tumours of unspecified malignancy (SMQ)</i>	Approved as Requested	English term	
Code#	20000201		<i>Ovarian tumours of unspecified malignancy (SMQ)</i>	20000201
Language	German		Code#	
			20000201	
			Language	
			German	
			Current translated term	
			<i>Tumoren der Eierstoecke unspezifischer Malignitaet (SMQ)</i>	
			Proposed new translation	
			<i>Tumoren der Eierstoecke nicht spezifizierter Malignitaet (SMQ)</i>	

MSSO Comment: The proposal to rename the German translation of the term Ovarian tumours of unspecified malignancy (SMQ) (Code: 20000201) from Tumoren der Eierstoecke unspezifischer Malignitaet (SMQ) to Tumoren der Eierstoecke nicht spezifizierter Malignitaet (SMQ) is approved as requested.

Supplemental Update Report

CR Number: 2015078988 Implementation Date: 20-May-15 Related CR: 2015078988

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Prostate tumours of unspecified malignancy (SMQ)</i>	Approved as Requested	English term	
Code#	20000203		<i>Prostate tumours of unspecified malignancy (SMQ)</i>	20000203
Language	German		Code#	
			20000203	
			Language	
			German	
			Current translated term	
			<i>Tumoren der Prostata unspezifischer Malignitaet (SMQ)</i>	
			Proposed new translation	
			<i>Tumoren der Prostata nicht spezifizierter Malignitaet (SMQ)</i>	

MSSO Comment: The proposal to rename the German translation of the term Prostate tumours of unspecified malignancy (SMQ) (Code: 20000203) from Tumoren der Prostata unspezifischer Malignitaet (SMQ) to Tumoren der Prostata nicht spezifizierter Malignitaet (SMQ) is approved as requested.

CR Number: 2015078989 Implementation Date: 20-May-15 Related CR: 2015078989

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Skin tumours of unspecified malignancy (SMQ)</i>	Approved as Requested	English term	
Code#	20000205		<i>Skin tumours of unspecified malignancy (SMQ)</i>	20000205
Language	German		Code#	
			20000205	
			Language	
			German	
			Current translated term	
			<i>Tumoren der Haut unspezifischer Malignitaet (SMQ)</i>	
			Proposed new translation	
			<i>Tumoren der Haut nicht spezifizierter Malignitaet (SMQ)</i>	

MSSO Comment: The proposal to rename the German translation of the term Skin tumours of unspecified malignancy (SMQ) (Code: 20000205) from Tumoren der Haut unspezifischer Malignitaet (SMQ) to Tumoren der Haut nicht spezifizierter Malignitaet (SMQ) is approved as requested.

Supplemental Update Report

CR Number: 2015078990

Implementation Date: 20-May-15

Related CR: 2015078990

<u>Change Requested</u>	<u>Rename Translated Term</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Liver tumours of unspecified malignancy (SMQ)</i>	Approved Not as Requested	English term	
Code#	20000209		<i>Liver tumours of unspecified malignancy (SMQ)</i>	20000209
Language	<i>German</i>		Code#	
			20000209	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Tumoren der Leber unspezifischer Malignitaet (SMQ)</i>	
			Proposed new translation	
			<i>Tumoren der Leber nicht spezifizierter Malignitaet (SMQ)</i>	

MSSO The proposal to rename the German translation of the term Liver tumours of unspecified malignancy (SMQ) (Code: 20000209) from Tumoren der Leber unspezifischer Malignitaet (SMQ) to to correct wrong translation of unspecified is approved but not as requested. This term will be translated as Tumoren der Leber nicht spezifizierter Malignitaet (SMQ).

Supplemental Update Report

CR Number: 2015079523

Implementation Date: 21-May-15

Related CR: 2015079523

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Acute alcoholic intoxication in alcoholism, unspecified drinking behavior</i>	Approved as Requested	English term <i>Acute alcoholic intoxication in alcoholism, unspecified drinking behavior</i>	10000654 Current
Code#	10000654		Code# 10000654	
Language	German		Language German Current translated term <i>akute Alkoholvergiftung bei existierender Alkoholkrankheit, unspezifisches Trinkverhalten</i> Proposed new translation <i>akute Alkoholvergiftung bei existierender Alkoholkrankheit, nicht spezifiziertes Trinkverhalten</i>	

MSSO Comment: The proposal to rename the German translation of the term Acute alcoholic intoxication in alcoholism, unspecified drinking behavior (Code: 10000654) from *akute Alkoholvergiftung bei existierender Alkoholkrankheit, unspezifisches Trinkverhalten* to *akute Alkoholvergiftung bei existierender Alkoholkrankheit, nicht spezifiziertes Trinkverhalten* is approved as requested.

Supplemental Update Report

CR Number: 2015079524

Implementation Date: 21-May-15

Related CR: 2015079524

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Alcohol abuse, unspecified drinking behavior*

Approved as Requested

English term

10001589 Current

Code# 10001589

Alcohol abuse, unspecified drinking behavior

Language *German*

Code#
10001589

Language
German

Current translated term
*Alkoholmissbrauch,
unspezifisches Trinkverhalten*

Proposed new translation
*Alkoholmissbrauch, nicht
spezifiziertes Trinkverhalten*

MSSO Comment: The proposal to rename the German translation of the term Alcohol abuse, unspecified drinking behavior (Code: 10001589) from Alkoholmissbrauch, unspezifisches Trinkverhalten to Alkoholmissbrauch, nicht spezifiziertes Trinkverhalten is approved as requested.

CR Number: 2015079525

Implementation Date: 21-May-15

Related CR: 2015079525

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Chronic or unspecified gastric ulcer with haemorrhage*

Approved as Requested

English term

10009047 Current

Code# 10009047

Chronic or unspecified gastric ulcer with haemorrhage

Language *German*

Code#
10009047

Language
German

Current translated term
*chronisches oder unspezifisches
Magengeschwuer mit Blutung*

Proposed new translation
*chronisches oder nicht
spezifiziertes Magengeschwuer
mit Blutung*

MSSO Comment: The proposal to rename the German translation of the term Chronic or unspecified gastric ulcer with haemorrhage (Code: 10009047) from chronisches oder unspezifisches Magengeschwuer mit Blutung to chronisches oder nicht spezifiziertes Magengeschwuer mit Blutung is approved as requested.

Supplemental Update Report

CR Number: 2015079526

Implementation Date: 21-May-15

Related CR: 2015079526

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Chronic or unspecified gastric ulcer with hemorrhage*

Approved as Requested

English term
Chronic or unspecified gastric ulcer with hemorrhage

10009049 Current

Code# 10009049

Code#
10009049

Language *German*

Language
German

Current translated term
chronisches oder unspezifisches Magengeschwuer mit Blutung

Proposed new translation
chronisches oder nicht spezifiziertes Magengeschwuer mit Blutung

MSSO Comment: The proposal to rename the German translation of the term Chronic or unspecified gastric ulcer with hemorrhage (Code: 10009049) from chronisches oder unspezifisches Magengeschwuer mit Blutung to chronisches oder nicht spezifiziertes Magengeschwuer mit Blutung is approved as requested.

Supplemental Update Report

CR Number: 2015079527

Implementation Date: 21-May-15

Related CR: 2015079527

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Chronic or unspecified gastrojejunal ulcer with haemorrhage</i>	Approved as Requested	English term <i>Chronic or unspecified gastrojejunal ulcer with haemorrhage</i>	10009058 Current
Code#	10009058		Code# 10009058	
Language	German		Language German	
			Current translated term <i>chronisches oder unspezifisches Gastrojejunalulkus mit Blutung</i>	
			Proposed new translation <i>chronisches oder nicht spezifiziertes Gastrojejunalulkus mit Blutung</i>	

MSSO Comment: The proposal to rename the German translation of the term Chronic or unspecified gastrojejunal ulcer with haemorrhage (Code: 10009058) from chronisches oder unspezifisches Gastrojejunalulkus mit Blutung to chronisches oder nicht spezifiziertes Gastrojejunalulkus mit Blutung is approved as requested.

Supplemental Update Report

CR Number: 2015079528

Implementation Date: 21-May-15

Related CR: 2015079528

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Chronic or unspecified gastrojejunal ulcer with hemorrhage</i>	Approved as Requested	English term	10009060 Current
Code#	10009060		<i>Chronic or unspecified gastrojejunal ulcer with hemorrhage</i>	
Language	German		Code#	
			10009060	
			Language	
			German	
			Current translated term	
			<i>chronisches oder unspezifisches Gastrojejunalulkus mit Blutung</i>	
			Proposed new translation	
			<i>chronisches oder nicht spezifiziertes Gastrojejunalulkus mit Blutung</i>	

MSSO Comment: The proposal to rename the German translation of the term Chronic or unspecified gastrojejunal ulcer with hemorrhage (Code: 10009060) from *chronisches oder unspezifisches Gastrojejunalulkus mit Blutung* to *chronisches oder nicht spezifiziertes Gastrojejunalulkus mit Blutung* is approved as requested.

Supplemental Update Report

CR Number: 2015079529

Implementation Date: 21-May-15

Related CR: 2015079529

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Metastases to urinary tract unspecified organ*

Approved as Requested

English term

10027472 Current

Code# 10027472

*Metastases to urinary tract
unspecified organ*

Language *German*

Code#
10027472

Language
German

Current translated term
*Metastasen des Harnwegs
unspezifisches Organ*

Proposed new translation
*Metastasen des Harnwegs nicht
spezifiziertes Organ*

MSSO Comment: The proposal to rename the German translation of the term Metastases to urinary tract unspecified organ (Code: 10027472) from Metastasen des Harnwegs unspezifisches Organ to Metastasen des Harnwegs nicht spezifiziertes Organ is approved as requested.

CR Number: 2015079530

Implementation Date: 21-May-15

Related CR: 2015079530

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Poisoning by unspecified antibiotic*

Approved as Requested

English term

10035986 Current

Code# 10035986

*Poisoning by unspecified
antibiotic*

Language *German*

Code#
10035986

Language
German

Current translated term
*Vergiftung durch ein
unspezifisches Antibiotikum*

Proposed new translation
*Vergiftung durch ein nicht
spezifiziertes Antibiotikum*

MSSO Comment: The proposal to rename the German translation of the term Poisoning by unspecified antibiotic (Code: 10035986) from Vergiftung durch ein unspezifisches Antibiotikum to Vergiftung durch ein nicht spezifiziertes Antibiotikum is approved as requested.

Supplemental Update Report

CR Number: 2015079531

Implementation Date: 21-May-15

Related CR: 2015079531

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Poisoning by unspecified drug or medicament</i>	Approved as Requested	English term	10035988 Current
Code#	10035988		<i>Poisoning by unspecified drug or medicament</i>	
Language	<i>German</i>		Code#	
			10035988	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Vergiftung durch ein unspezifisches Arzneimittel oder Medikament</i>	
			Proposed new translation	
			<i>Vergiftung durch ein nicht spezifiziertes Arzneimittel oder Medikament</i>	

MSSO Comment: The proposal to rename the German translation of the term Poisoning by unspecified drug or medicament (Code: 10035988) from Vergiftung durch ein unspezifisches Arzneimittel oder Medikament to Vergiftung durch ein nicht spezifiziertes Arzneimittel oder Medikament is approved as requested.

Supplemental Update Report

CR Number: 2015079532

Implementation Date: 21-May-15

Related CR: 2015079532

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Poisoning by unspecified drug or medicinal substance</i>	Approved as Requested	English term <i>Poisoning by unspecified drug or medicinal substance</i>	10035989 Current
Code#	10035989		Code# 10035989	
Language	German		Language German	
			Current translated term <i>Vergiftung durch ein unspezifisches Arzneimittel oder medizinische Substanz</i>	
			Proposed new translation <i>Vergiftung durch ein nicht spezifiziertes Arzneimittel oder medizinische Substanz</i>	

MSSO Comment: The proposal to rename the German translation of the term Poisoning by unspecified drug or medicinal substance (Code: 10035989) from Vergiftung durch ein unspezifisches Arzneimittel oder medizinische Substanz to Vergiftung durch ein nicht spezifiziertes Arzneimittel oder medizinische Substanz is approved as requested.

Supplemental Update Report

CR Number: 2015079533

Implementation Date: 21-May-15

Related CR: 2015079533

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Poisoning by unspecified drug primarily affecting autonomic nervous system</i>	Approved Not as Requested	English term <i>Poisoning by unspecified drug primarily affecting autonomic nervous system</i>	10035990 Current
Code#	10035990		Code# 10035990	
Language	German		Language German	
			Current translated term <i>Vergiftung durch unspezifisches, hauptsaechlich auf das autonome Nervensystem einwirkendes Mittel</i>	
			Proposed new translation <i>Vergiftung durch nicht spezif, hauptsaechlich auf das autonome Nervensystem einwirkendes Mittel</i>	

MSSO Comment: The proposal to rename the German translation of the term Poisoning by unspecified drug primarily affecting autonomic nervous system (Code: 10035990) from Vergiftung durch unspezifisches, hauptsaechlich auf das autonome Nervensystem einwirkendes Mittel to Vergiftung durch nicht spezifiziertes, hauptsaechlich auf das autonome Nervensystem einwirkendes Mit is approved but not as requested. The German translation for this term will be changed to Vergiftung durch nicht spezif, hauptsaechlich auf das autonome Nervensystem einwirkendes Mittel.

Supplemental Update Report

CR Number: 2015079534

Implementation Date: 21-May-15

Related CR: 2015079534

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Acute alcoholic intoxication in alcoholism, unspecified drinking behaviour</i>	Approved as Requested	English term <i>Acute alcoholic intoxication in alcoholism, unspecified drinking behaviour</i>	10063498 Current
Code#	10063498		Code# 10063498	
Language	German		Language German Current translated term <i>akute Alkoholvergiftung bei existierender Alkoholkrankheit, unspezifisches Trinkverhalten</i> Proposed new translation <i>akute Alkoholvergiftung bei existierender Alkoholkrankheit, nicht spezifiziertes Trinkverhalten</i>	

MSSO Comment: The proposal to rename the German translation of the term Acute alcoholic intoxication in alcoholism, unspecified drinking behaviour (Code: 10063498) from akute Alkoholvergiftung bei existierender Alkoholkrankheit, unspezifisches Trinkverhalten to akute Alkoholvergiftung bei existierender Alkoholkrankheit, nicht spezifiziertes Trinkverhalten is approved as requested.

Supplemental Update Report

CR Number: 2015079535 Implementation Date: 21-May-15 Related CR: 2015079535

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Alcohol abuse, unspecified drinking behaviour</i>	Approved as Requested	English term	10063501 Current
Code#	10063501		<i>Alcohol abuse, unspecified drinking behaviour</i>	
Language	<i>German</i>		Code#	
			10063501	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Alkoholkrankheit, unspezifisches Trinkverhalten</i>	
			Proposed new translation	
			<i>Alkoholkrankheit, nicht spezifiziertes Trinkverhalten</i>	

MSSO Comment: The proposal to rename the German translation of the term Alcohol abuse, unspecified drinking behaviour (Code: 10063501) from Alkoholkrankheit, unspezifisches Trinkverhalten to Alkoholkrankheit, nicht spezifiziertes Trinkverhalten is approved as requested.

CR Number: 2015079536 Implementation Date: 21-May-15 Related CR: 2015079536

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Carcinoma in situ of anus, unspecified</i>	Approved as Requested	English term	10007355 Current
Code#	10007355		<i>Carcinoma in situ of anus, unspecified</i>	
Language	<i>German</i>		Code#	
			10007355	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Karzinom in situ des Anus, ubspezifisch</i>	
			Proposed new translation	
			<i>Karzinom in situ des Anus, nicht spezifiziert</i>	

MSSO Comment: The proposal to rename the German translation of the term Carcinoma in situ of anus, unspecified (Code: 10007355) from Karzinom in situ des Anus, ubspezifisch to Karzinom in situ des Anus, nicht spezifiziert is approved as requested.

Supplemental Update Report

CR Number: 2015079537 Implementation Date: 21-May-15 Related CR: 2015079537

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Clinical anophthalmos, unspecified</i>	Approved as Requested	English term	10009298 Current
Code#	10009298		<i>Clinical anophthalmos, unspecified</i>	
Language	German		Code#	
			10009298	
			Language	
			German	
			Current translated term	
			<i>klinischer Anophthalmus, spezifisch</i>	
			Proposed new translation	
			<i>klinischer Anophthalmus, nicht spezifiziert</i>	

MSSO Comment: The proposal to rename the German translation of the term Clinical anophthalmos, unspecified (Code: 10009298) from klinischer Anophthalmus, spezifisch to klinischer Anophthalmus, nicht spezifiziert is approved as requested.

CR Number: 2015079538 Implementation Date: 21-May-15 Related CR: 2015079538

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Hereditary corneal dystrophy, unspecified</i>	Approved as Requested	English term	10019868 Current
Code#	10019868		<i>Hereditary corneal dystrophy, unspecified</i>	
Language	German		Code#	
			10019868	
			Language	
			German	
			Current translated term	
			<i>hereditaere Dystrophie der Hornhaut</i>	
			Proposed new translation	
			<i>hereditaere Dystrophie der Hornhaut nicht naeher bezeichnet</i>	

MSSO Comment: The proposal to rename the German translation of the term Hereditary corneal dystrophy, unspecified (Code: 10019868) from hereditaere Dystrophie der Hornhaut to hereditaere Dystrophie der Hornhaut nicht naeher bezeichnet is approved as requested.

Supplemental Update Report

CR Number: 2015079539 Implementation Date: 21-May-15 Related CR: 2015079539

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Hernia of unspecified site without mention of obstruction or gangrene</i>	Approved as Requested	English term <i>Hernia of unspecified site without mention of obstruction or gangrene</i>	10019927 Current
Code#	10019927		Code# 10019927	
Language	German		Language German Current translated term <i>Hernie an sonstigen spezifischen Stellen, ohne Erwaechnung von Obstruktion oder Gangraen</i> Proposed new translation <i>Hernie ohne Angabe der Lokalisation, ohne Erwaechnung von Obstruktion oder Gangraen</i>	

MSSO Comment: The proposal to rename the German translation of the term Hernia of unspecified site without mention of obstruction or gangrene (Code: 10019927) from Hernie an sonstigen spezifischen Stellen, ohne Erwaechnung von Obstruktion oder Gangraen to Hernie ohne Angabe der Lokalisation, ohne Erwaechnung von Obstruktion oder Gangraen is approved as requested.

CR Number: 2015079540 Implementation Date: 21-May-15 Related CR: 2015079540

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Hydrocele, unspecified</i>	Approved as Requested	English term <i>Hydrocele, unspecified</i>	10020502 Current
Code#	10020502		Code# 10020502	
Language	German		Language German Current translated term <i>Hydrozele, unspezifisch</i> Proposed new translation <i>Hydrozele, ohne naehere Angabe</i>	

MSSO Comment: The proposal to rename the German translation of the term Hydrocele, unspecified (Code: 10020502) from Hydrozele, unspezifisch to Hydrozele, ohne naehere Angabe is approved as requested.

Supplemental Update Report

CR Number: 2015079541

Implementation Date: 21-May-15

Related CR: 2015079541

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Infective otitis externa, unspecified*

Approved as Requested

English term
*Infective otitis externa,
unspecified*

10021920 Current

Code# 10021920

Code#
10021920

Language *German*

Language
German

Current translated term
*infektioese Otitis externa,
unspezifisch*

Proposed new translation
*infektioese Otitis externa, nicht
spezifiziert*

MSSO Comment: The proposal to rename the German translation of the term Infective otitis externa, unspecified (Code: 10021920) from infektioese Otitis externa, unspezifisch to infektioese Otitis externa, nicht spezifiziert is approved as requested.

Supplemental Update Report

CR Number: 2015079542

Implementation Date: 21-May-15

Related CR: 2015079542

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Monoplegia of lower limb affecting unspecified side* Approved as Requested
Code# 10027930
Language *German*

English term
Monoplegia of lower limb affecting unspecified side 10027930 Current
Code#
10027930
Language
German
Current translated term
Monoplegie einer unteren Gliedmasse mit Auswirkung auf die dominante Seite
Proposed new translation
Monoplegie einer unteren Gliedmasse ohne Angabe der betroffenen Seite

MSSO Comment: The proposal to rename the German translation of the term Monoplegia of lower limb affecting unspecified side (Code: 10027930) from Monoplegie einer unteren Gliedmasse mit Auswirkung auf die dominante Seite to Monoplegie einer unteren Gliedmasse ohne Angabe der betroffenen Seite is approved as requested.

Supplemental Update Report

CR Number: 2015079543 Implementation Date: 21-May-15 Related CR: 2015079543

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Paranoid type schizophrenia, unspecified state</i>	Approved as Requested	English term	10033883 Current
Code#	10033883		<i>Paranoid type schizophrenia, unspecified state</i>	
Language	<i>German</i>		Code#	
			10033883	
			Language	
			<i>German</i>	
			Current translated term	
			<i>paranoide Form der Schizophrenie,unspezifischer Zustand</i>	
			Proposed new translation	
			<i>paranoide Form der Schizophrenie, ohne Angabe des Stadiums</i>	

MSSO Comment: The proposal to rename the German translation of the term Paranoid type schizophrenia, unspecified state (Code: 10033883) from paranoide Form der Schizophrenie,unspezifischer Zustand to paranoide Form der Schizophrenie, ohne Angabe des Stadiums is approved as requested.

CR Number: 2015079544 Implementation Date: 21-May-15 Related CR: 2015079544

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Rupture of synovium, unspecified</i>	Approved as Requested	English term	10039312 Current
Code#	10039312		<i>Rupture of synovium, unspecified</i>	
Language	<i>German</i>		Code#	
			10039312	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Ruptur der Synovialis</i>	
			Proposed new translation	
			<i>Ruptur der Synovialis nicht spezifiziert</i>	

MSSO Comment: The proposal to rename the German translation of the term Rupture of synovium, unspecified (Code: 10039312) from Ruptur der Synovialis to Ruptur der Synovialis nicht spezifiziert is approved as requested.

Supplemental Update Report

CR Number: 2015079545 Implementation Date: 21-May-15 Related CR: 2015079545

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Thrombocytopenia, unspecified</i>	Approved as Requested	English term	
Code#	10043560		<i>Thrombocytopenia, unspecified</i>	10043560 Current
Language	<i>German</i>		Code#	
			10043560	
			Language	
			<i>German</i>	
			Current translated term	
			<i>Thrombozytopenie, unsepezifisch</i>	
			Proposed new translation	
			<i>Thrombozytopenie, unsepezifiziert</i>	

MSSO Comment: The proposal to rename the German translation of the term Thrombocytopenia, unspecified (Code: 10043560) from Thrombozytopenie, unsepezifisch to Thrombozytopenie, unsepezifiziert is approved as requested.

CR Number: 2015079546 Implementation Date: 21-May-15 Related CR: 2015079546

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Toxic effect of caustic, unspecified</i>	Approved as Requested	English term	
Code#	10044160		<i>Toxic effect of caustic, unspecified</i>	10044160 Current
Language	<i>German</i>		Code#	
			10044160	
			Language	
			<i>German</i>	
			Current translated term	
			<i>toxische Wirkung von Aetzmitteln</i>	
			Proposed new translation	
			<i>toxische Wirkung von Aetzmitteln, unsepezifiziert</i>	

MSSO Comment: The proposal to rename the German translation of the term Toxic effect of caustic, unspecified (Code: 10044160) from toxische Wirkung von Aetzmitteln to toxische Wirkung von Aetzmitteln, unsepezifiziert is approved as requested.

Supplemental Update Report

CR Number: 2015079547 Implementation Date: 21-May-15 Related CR: 2015079547

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Toxic effect of unspecified alcohol</i>	Approved as Requested	English term	10044213 Current
Code#	10044213		<i>Toxic effect of unspecified alcohol</i>	
Language	<i>German</i>		Code#	
			10044213	
			Language	
			<i>German</i>	
			Current translated term	
			<i>toxischer Effekt von unspezifischem Alkohol</i>	
			Proposed new translation	
			<i>toxischer Effekt von unspezifiziertem Alkohol</i>	

MSSO Comment: The proposal to rename the German translation of the term Toxic effect of unspecified alcohol (Code: 10044213) from toxischer Effekt von unspezifischem Alkohol to toxischer Effekt von unspezifiziertem Alkohol is approved as requested.

CR Number: 2015079548 Implementation Date: 21-May-15 Related CR: 2015079548

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified anomaly of jaw size</i>	Approved as Requested	English term	10045629 Current
Code#	10045629		<i>Unspecified anomaly of jaw size</i>	
Language	<i>German</i>		Code#	
			10045629	
			Language	
			<i>German</i>	
			Current translated term	
			<i>sonstige spezifische Anomalie der Kiefergroesse</i>	
			Proposed new translation	
			<i>sonstige nicht spezifizierte Anomalie der Kiefergroesse</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified anomaly of jaw size (Code: 10045629) from sonstige spezifische Anomalie der Kiefergroesse to sonstige nicht spezifizierte Anomalie der Kiefergroesse is approved as requested.

Supplemental Update Report

CR Number: 2015079549 Implementation Date: 21-May-15 Related CR: 2015079549

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified anterior horn cell disease</i>	Approved as Requested	English term	
Code#	10045639		<i>Unspecified anterior horn cell disease</i>	10045639 Current
Language	<i>German</i>		Code#	
			10045639	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifisches Erkrankung des Vorderhorns</i>	
			Proposed new translation	
			<i>nicht naeher bezeichnete Erkrankung des Vorderhorns</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified anterior horn cell disease (Code: 10045639) from unspezifisches Erkrankung des Vorderhorns to nicht naeher bezeichnete Erkrankung des Vorderhorns is approved as requested.

CR Number: 2015079550 Implementation Date: 21-May-15 Related CR: 2015079550

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified birth trauma</i>	Approved as Requested	English term	
Code#	10045644		<i>Unspecified birth trauma</i>	10045644 Current
Language	<i>German</i>		Code#	
			10045644	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifisches Geburtstrauma</i>	
			Proposed new translation	
			<i>nicht naeher bezeichnetes Geburtstrauma</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified birth trauma (Code: 10045644) from unspezifisches Geburtstrauma to nicht naeher bezeichnetes Geburtstrauma is approved as requested.

Supplemental Update Report

CR Number: 2015079551

Implementation Date: 21-May-15

Related CR: 2015079551

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	Rename Translated Term <i>Unspecified disease of larynx</i>	Approved Not as Requested	English term <i>Unspecified disease of larynx</i>	10045749 Current
Code#	<i>10045749</i>		Code# <i>10045749</i>	
Language	<i>German</i>		Language <i>German</i>	
			Current translated term <i>nicht naeher bezeichnete Erkrankung der Larynx</i>	
			Proposed new translation <i>nicht spezifizierte Erkrankung der Larynx</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified disease of larynx (Code: 10045749) from nicht naeher bezeichnete Erkrankung der Larynx to nicht naeher bezeichnete Erkrankung der Larynx is approved but not as requested. The German translation of this term will be changed to nicht spezifizierte Erkrankung der Larynx.

Supplemental Update Report

CR Number: 2015079552

Implementation Date: 21-May-15

Related CR: 2015079552

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified drug-induced mental disorder</i>	Approved as Requested	English term	10045856 Current
Code#	10045856		<i>Unspecified drug-induced mental disorder</i>	
Language	<i>German</i>		Code#	
			10045856	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifische, von Arzneimitteln hervorgerufene psychische Stoerung</i>	
			Proposed new translation	
			<i>nicht naeher bezeichnete, von Arzneimitteln hervorgerufene psychische Stoerung</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified drug-induced mental disorder (Code: 10045856) from *unspezifische, von Arzneimitteln hervorgerufene psychische Stoerung* to *nicht naeher bezeichnete, von Arzneimitteln hervorgerufene psychische Stoerung* is approved as requested.

Supplemental Update Report

CR Number: 2015079553	Implementation Date: 21-May-15	Related CR: 2015079553		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified Eustachian tube disorder</i>	Approved as Requested	English term	
Code#	10045867		<i>Unspecified Eustachian tube disorder</i>	10045867 Current
Language	<i>German</i>		Code#	
			10045867	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifisch Tuba eustachii Erkrankung</i>	
			Proposed new translation	
			<i>nicht naeher bezeichnete Erkrankung der eustachischen Tube</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified Eustachian tube disorder (Code: 10045867) from unspezifisch Tuba eustachii Erkrankung to nicht naeher bezeichnete Erkrankung der eustachischen Tube is approved as requested.

CR Number: 2015079554	Implementation Date: 21-May-15	Related CR: 2015079554		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified glaucoma</i>	Approved as Requested	English term	
Code#	10045894		<i>Unspecified glaucoma</i>	10045894 Current
Language	<i>German</i>		Code#	
			10045894	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifisches Glaukom</i>	
			Proposed new translation	
			<i>nicht naeher bezeichnetes Glaukom</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified glaucoma (Code: 10045894) from unspezifisches Glaukom to nicht naeher bezeichnetes Glaukom is approved as requested.

Supplemental Update Report

CR Number: 2015079555 Implementation Date: 21-May-15 Related CR: 2015079555

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified leukemia in remission</i>	Approved Not as Requested	English term	10045993 Current
Code#	10045993		<i>Unspecified leukemia in remission</i>	
Language	German		Code#	
			10045993	
			Language	
			German	
			Current translated term	
			<i>nicht spezifische Leukaemie (in Remission)</i>	
			Proposed new translation	
			<i>nicht spezifizierte Leukaemie (in Remission)</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified leukemia in remission (Code: 10045993) from nicht spezifische Leukaemie (in Remission) to nicht spezifische Leukaemie (in Remission) is approved but not as requested. The German translation for this term will be changed to nicht spezifizierte Leukaemie (in Remission).

CR Number: 2015079556 Implementation Date: 21-May-15 Related CR: 2015079556

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified obstetrical trauma</i>	Approved as Requested	English term	10046059 Current
Code#	10046059		<i>Unspecified obstetrical trauma</i>	
Language	German		Code#	
			10046059	
			Language	
			German	
			Current translated term	
			<i>unspezifisches Trauma bei der Entbindung</i>	
			Proposed new translation	
			<i>nicht naeher bezeichnetes Trauma bei der Entbindung</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified obstetrical trauma (Code: 10046059) from unspezifisches Trauma bei der Entbindung to nicht naeher bezeichnetes Trauma bei der Entbindung is approved as requested.

Supplemental Update Report

CR Number: 2015079557

Implementation Date: 21-May-15

Related CR: 2015079557

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified obstetrical trauma, antepartum*

Approved as Requested

English term

10046060 Current

Code# 10046060

Unspecified obstetrical trauma, antepartum

Language *German*

Code#
10046060

Language
German

Current translated term

unspezifisches Trauma bei der Entbindung, antepartal

Proposed new translation

nicht naeher bezeichnetes Trauma bei der Entbindung, antepartal

MSSO Comment: The proposal to rename the German translation of the term Unspecified obstetrical trauma, antepartum (Code: 10046060) from unspezifisches Trauma bei der Entbindung, antepartal to nicht naeher bezeichnetes Trauma bei der Entbindung, antepartal is approved as requested.

Supplemental Update Report

CR Number: 2015079558

Implementation Date: 21-May-15

Related CR: 2015079558

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified obstetrical trauma, delivered, with postpartum complication</i>	Approved as Requested	English term <i>Unspecified obstetrical trauma, delivered, with postpartum complication</i>	10046061 Current
Code#	10046061		Code# 10046061	
Language	German		Language German Current translated term <i>unspezifisches Trauma bei der Entbindung, entbunden, mit postpartaler Komplikation</i> Proposed new translation <i>nicht spezifiziertes Trauma bei der Entbindung, entbunden, mit postpartaler Komplikation</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified obstetrical trauma, delivered, with postpartum complication (Code: 10046061) from unspezifisches Trauma bei der Entbindung, entbunden, mit postpartaler Komplikation to nicht spezifiziertes Trauma bei der Entbindung, entbunden, mit postpartaler Komplikation is approved as requested.

Supplemental Update Report

CR Number: 2015079559 Implementation Date: 21-May-15 Related CR: 2015079559

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified obstetrical trauma, postpartum</i>	Approved as Requested	English term	10046062 Current
Code#	10046062		<i>Unspecified obstetrical trauma, postpartum</i>	
Language	German		Code#	
			10046062	
			Language	
			German	
			Current translated term	
			<i>unspezifisches Trauma bei der Entbindung, postpartal</i>	
			Proposed new translation	
			<i>nicht spezifiziertes Trauma bei der Entbindung, postpartal</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified obstetrical trauma, postpartum (Code: 10046062) from unspezifisches Trauma bei der Entbindung, postpartal to nicht spezifiziertes Trauma bei der Entbindung, postpartal is approved as requested.

CR Number: 2015079560 Implementation Date: 21-May-15 Related CR: 2015079560

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified obstetrical trauma, with delivery</i>	Approved as Requested	English term	10046064 Current
Code#	10046064		<i>Unspecified obstetrical trauma, with delivery</i>	
Language	German		Code#	
			10046064	
			Language	
			German	
			Current translated term	
			<i>unspezifisches Trauma bei der Entbindung, bei Entbindung</i>	
			Proposed new translation	
			<i>nicht spezifiziertes Trauma bei der Entbindung, bei Entbindung</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified obstetrical trauma, with delivery (Code: 10046064) from unspezifisches Trauma bei der Entbindung, bei Entbindung to nicht spezifiziertes Trauma bei der Entbindung, bei Entbindung is approved as requested.

Supplemental Update Report

CR Number: 2015079561

Implementation Date: 21-May-15

Related CR: 2015079561

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified organic brain syndrome (chronic)*

Approved as Requested

English term
*Unspecified organic brain
syndrome (chronic)*

10046074 Current

Code# *10046074*

Code#
10046074

Language *German*

Language
German

Current translated term
*unspezifisches organisches
Hirnsyndrom (chronisch)*

Proposed new translation
*nicht spezifiziertes organisches
Hirnsyndrom (chronisch)*

MSSO Comment: The proposal to rename the German translation of the term Unspecified organic brain syndrome (chronic) (Code: 10046074) from unspezifisches organisches Hirnsyndrom (chronisch) to nicht spezifiziertes organisches Hirnsyndrom (chronisch) is approved as requested.

Supplemental Update Report

CR Number: 2015079562 Implementation Date: 21-May-15 Related CR: 2015079562

Change Requested	Rename Translated Term	Final Disposition	Final Placement	MedDRA Code #
English term	<i>Unspecified protozoal intestinal disease</i>	Approved as Requested	English term	10046118 Current
Code#	10046118		<i>Unspecified protozoal intestinal disease</i>	
Language	<i>German</i>		Code#	
			10046118	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifische, durch Protozoen verursachte Erkrankung des Darms</i>	
			Proposed new translation	
			<i>nicht spezifizierte, durch Protozoen verursachte Erkrankung des Darms</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified protozoal intestinal disease (Code: 10046118) from unspezifische, durch Protozoen verursachte Erkrankung des Darms to nicht spezifizierte, durch Protozoen verursachte Erkrankung des Darms is approved as requested.

CR Number: 2015079563 Implementation Date: 21-May-15 Related CR: 2015079563

Change Requested	Rename Translated Term	Final Disposition	Final Placement	MedDRA Code #
English term	<i>Unspecified rat-bite fever</i>	Approved as Requested	English term	10046131 Current
Code#	10046131		<i>Unspecified rat-bite fever</i>	
Language	<i>German</i>		Code#	
			10046131	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifisches Rattenbissfieber</i>	
			Proposed new translation	
			<i>nicht spezifiziertes Rattenbissfieber</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified rat-bite fever (Code: 10046131) from unspezifisches Rattenbissfieber to nicht spezifiziertes Rattenbissfieber is approved as requested.

Supplemental Update Report

CR Number: 2015079564	Implementation Date: 21-May-15	Related CR: 2015079564		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified relapsing fever</i>	Approved as Requested	English term	
Code#	10046134		<i>Unspecified relapsing fever</i>	10046134 Current
Language	<i>German</i>		Code#	
			10046134	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifisches Rueckfallfieber</i>	
			Proposed new translation	
			<i>nicht spezifiziertes Rueckfallfieber</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified relapsing fever (Code: 10046134) from unspezifisches Rueckfallfieber to nicht spezifiziertes Rueckfallfieber is approved as requested.

CR Number: 2015079565	Implementation Date: 21-May-15	Related CR: 2015079565		
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified trauma to perineum and vulva during delivery</i>	Approved as Requested	English term	
Code#	10046186		<i>Unspecified trauma to perineum and vulva during delivery</i>	10046186 Current
Language	<i>German</i>		Code#	
			10046186	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifisches Trauma von Perineum und Vulva waehrend der Entbindung</i>	
			Proposed new translation	
			<i>nicht spezifiziertes Trauma von Perineum und Vulva waehrend der Entbindung</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified trauma to perineum and vulva during delivery (Code: 10046186) from unspezifisches Trauma von Perineum und Vulva waehrend der Entbindung to nicht spezifiziertes Trauma von Perineum und Vulva waehrend der Entbindung is approved as requested.

Supplemental Update Report

CR Number: 2015079566

Implementation Date: 21-May-15

Related CR: 2015079566

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified trauma to perineum and vulva, postpartum*

Approved as Requested

English term
Unspecified trauma to perineum and vulva, postpartum

10046187 Current

Code# 10046187

Language *German*

Code#
10046187

Language
German

Current translated term
unspezifisches Trauma von Perineum und Vulva, postpartal

Proposed new translation
nicht spezifiziertes Trauma von Perineum und Vulva, postpartal

MSSO Comment: The proposal to rename the German translation of the term Unspecified trauma to perineum and vulva, postpartum (Code: 10046187) from unspezifisches Trauma von Perineum und Vulva, postpartal to nicht spezifiziertes Trauma von Perineum und Vulva, postpartal is approved as requested.

Supplemental Update Report

CR Number: 2015079567

Implementation Date: 21-May-15

Related CR: 2015079567

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified trauma to perineum and vulva, with delivery</i>	Approved as Requested	English term <i>Unspecified trauma to perineum and vulva, with delivery</i>	10046189 Current
Code#	10046189		Code# 10046189	
Language	German		Language German	
			Current translated term <i>unspezifisches Trauma von Perineum und Vulva, bei Entbindung</i>	
			Proposed new translation <i>nicht spezifiziertes Trauma von Perineum und Vulva, bei Entbindung</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified trauma to perineum and vulva, with delivery (Code: 10046189) from unspezifisches Trauma von Perineum und Vulva, bei Entbindung to nicht spezifiziertes Trauma von Perineum und Vulva, bei Entbindung is approved as requested.

Supplemental Update Report

CR Number: 2015079568 Implementation Date: 21-May-15 Related CR: 2015079568

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified type maternal pyrexia, antepartum</i>	Approved as Requested	English term	10046202 Current
Code#	10046202		<i>Unspecified type maternal pyrexia, antepartum</i>	
Language	German		Code#	
			10046202	
			Language	
			German	
			Current translated term	
			<i>unspezifisches Fieber der Mutter, antepartal</i>	
			Proposed new translation	
			<i>nicht spezifiziertes Fieber der Mutter, antepartal</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified type maternal pyrexia, antepartum (Code: 10046202) from unspezifisches Fieber der Mutter, antepartal to nicht spezifiziertes Fieber der Mutter, antepartal is approved as requested.

CR Number: 2015079569 Implementation Date: 21-May-15 Related CR: 2015079569

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified vomiting of pregnancy</i>	Approved as Requested	English term	10046244 Current
Code#	10046244		<i>Unspecified vomiting of pregnancy</i>	
Language	German		Code#	
			10046244	
			Language	
			German	
			Current translated term	
			<i>unspezifisches Schwangerschaftserbrechen</i>	
			Proposed new translation	
			<i>nicht spezifiziertes Schwangerschaftserbrechen</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified vomiting of pregnancy (Code: 10046244) from unspezifisches Schwangerschaftserbrechen to nicht spezifiziertes Schwangerschaftserbrechen is approved as requested.

Supplemental Update Report

CR Number: 2015079570

Implementation Date: 21-May-15

Related CR: 2015079570

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified vomiting of pregnancy, antepartum*
Code# *10046245*
Language *German*

Approved as Requested

English term
Unspecified vomiting of pregnancy, antepartum
Code#
10046245
Language
German
Current translated term
unspezifisches Schwangerschaftserbrechen, antepartal
Proposed new translation
nicht spezifiziertes Schwangerschaftserbrechen, antepartal

10046245 Current

MSSO The proposal to rename the German translation of the term Unspecified vomiting of pregnancy, antepartum (Code: 10046245) from unspezifisches Schwangerschaftserbrechen, antepartal to nicht spezifiziertes Schwangerschaftserbrechen, antepartal is approved as requested.

Comment:

Supplemental Update Report

CR Number: 2015079571

Implementation Date: 21-May-15

Related CR: 2015079571

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Unspecified vomiting of pregnancy, delivered</i>	Approved as Requested	English term	10046246 Current
Code#	10046246		<i>Unspecified vomiting of pregnancy, delivered</i>	
Language	<i>German</i>		Code#	
			10046246	
			Language	
			<i>German</i>	
			Current translated term	
			<i>unspezifisches Schwangerschaftserbrechen, entbunden</i>	
			Proposed new translation	
			<i>nicht spezifiziertes Schwangerschaftserbrechen, entbunden</i>	

MSSO Comment: The proposal to rename the German translation of the term Unspecified vomiting of pregnancy, delivered (Code: 10046246) from unspezifisches Schwangerschaftserbrechen, entbunden to nicht spezifiziertes Schwangerschaftserbrechen, entbunden is approved as requested.

Supplemental Update Report

CR Number: 2015079572

Implementation Date: 21-May-15

Related CR: 2015079572

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified vomiting of pregnancy, unspecified as to episode of care* Approved as Requested
Code# 10046247
Language German

English term *Unspecified vomiting of pregnancy, unspecified as to episode of care* 10046247 Current
Code# 10046247
Language German
Current translated term *unspezifisches Schwangerschaftserbrechen, ohne Angabe der Behandlungsepisode*
Proposed new translation *nicht spezifiziertes Schwangerschaftserbrechen, ohne Angabe der Behandlungsepisode*

MSSO Comment: The proposal to rename the German translation of the term Unspecified vomiting of pregnancy, unspecified as to episode of care (Code: 10046247) from unspezifisches Schwangerschaftserbrechen, ohne Angabe der Behandlungsepisode to nicht spezifiziertes Schwangerschaftserbrechen, ohne Angabe der Behandlungsepisode is approved as requested.

Supplemental Update Report

CR Number: 2015079573

Implementation Date: 21-May-15

Related CR: 2015079573

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Unspecified yellow fever*

Approved as Requested

English term

10046248 Current

Code# 10046248

Unspecified yellow fever

Language *German*

Code#
10046248

Language
German

Current translated term
unspezifisches Gelbfieber

Proposed new translation
nicht spezifiziertes Gelbfieber

MSSO Comment: The proposal to rename the German translation of the term Unspecified yellow fever (Code: 10046248) from unspezifisches Gelbfieber to nicht spezifiziertes Gelbfieber is approved as requested.

CR Number: 2015079574

Implementation Date: 21-May-15

Related CR: 2015079574

Change Requested

Rename Translated Term

Final Disposition

Final Placement

MedDRA
Code #

English term *Exposure to unspecified agent*

Approved as Requested

English term

10073305

Code# 10073305

Exposure to unspecified agent

Language *German*

Code#
10073305

Language
German

Current translated term
*Exposition gegenueber einem
unspezifischem Mittel*

Proposed new translation
*Exposition gegenueber einer
unbekannten Substanz*

MSSO Comment: The proposal to rename the German translation of the term Exposure to unspecified agent (Code: 10073305) from Exposition gegenueber einem unspezifischem Mittel to Exposition gegenueber einer unbekanntn Substanz is approved as requested.

Supplemental Update Report

CR Number: 2015079575 Implementation Date: 21-May-15 Related CR: 2015079575

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Uterine and fallopian tube tumours of unspecified malignancy (SMQ)</i>	Approved as Requested	English term <i>Uterine and fallopian tube tumours of unspecified malignancy (SMQ)</i>	20000207
Code#	20000207		Code# 20000207	
Language	German		Language German	
			Current translated term <i>Maligne Tumoren des Uterus und der Eileiter (SMQ)</i>	
			Proposed new translation <i>Tumoren des Uterus und der Eileiter ohne Angabe der Malignitaet (SMQ)</i>	

MSSO Comment: The proposal to rename the German translation of the term Uterine and fallopian tube tumours of unspecified malignancy (SMQ) (Code: 20000207) from Maligne Tumoren des Uterus und der Eileiter (SMQ) to Tumoren des Uterus und der Eileiter ohne Angabe der Malignitaet (SMQ) is approved as requested.

CR Number: 2015126002 Implementation Date: 22-May-15 Related CR: 2015126002

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter blockage</i>	Approved as Requested	English term <i>Catheter blockage</i>	10052255 Current
Code#	10052255		Code# 10052255	
Language	Chinese		Language Chinese	
			Current translated term <i>导尿管闭锁</i>	
			Proposed new translation <i>导管闭锁</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter blockage (Code: 10052255) from 导尿管闭锁 to 导管闭锁 is approved as requested.

Supplemental Update Report

CR Number: 2015126003 Implementation Date: 22-May-15 Related CR: 2015126003

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter occlusion</i>	Approved as Requested	English term	
Code#	10051149		<i>Catheter occlusion</i>	10051149 Current
Language	<i>Chinese</i>		Code#	
			10051149	
			Language	
			<i>Chinese</i>	
			Current translated term	
			<i>导尿管闭塞</i>	
			Proposed new translation	
			<i>导管闭塞</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter occlusion (Code: 10051149) from 导尿管闭塞 to 导管闭塞 is approved as requested.

CR Number: 2015126004 Implementation Date: 22-May-15 Related CR: 2015126004

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter site bleeding</i>	Approved as Requested	English term	
Code#	10051109		<i>Catheter site bleeding</i>	10051109 Current
Language	<i>Chinese</i>		Code#	
			10051109	
			Language	
			<i>Chinese</i>	
			Current translated term	
			<i>导尿管部位出血</i>	
			Proposed new translation	
			<i>导管部位出血</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter site bleeding (Code: 10051109) from 导尿管部位出血 to 导管部位出血 is approved as requested.

Supplemental Update Report

CR Number: 2015126005 Implementation Date: 22-May-15 Related CR: 2015126005

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter site burning</i>	Approved as Requested	English term	
Code#	10064621		<i>Catheter site burning</i>	10064621 Current
Language	<i>Chinese</i>		Code#	
			10064621	
			Language	
			<i>Chinese</i>	
			Current translated term	
			<i>导尿管部位烧灼</i>	
			Proposed new translation	
			<i>导管部位烧灼</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter site burning (Code: 10064621) from 导尿管部位烧灼 to 导管部位烧灼 is approved as requested.

CR Number: 2015126006 Implementation Date: 22-May-15 Related CR: 2015126006

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter site discomfort</i>	Approved as Requested	English term	
Code#	10054232		<i>Catheter site discomfort</i>	10054232 Current
Language	<i>Chinese</i>		Code#	
			10054232	
			Language	
			<i>Chinese</i>	
			Current translated term	
			<i>导尿管位点不适</i>	
			Proposed new translation	
			<i>导管位点不适</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter site discomfort (Code: 10054232) from 导尿管位点不适 to 导管位点不适 is approved as requested.

Supplemental Update Report

CR Number: 2015126007 Implementation Date: 22-May-15 Related CR: 2015126007

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter site ecchymosis</i>	Approved as Requested	English term	
Code#	10052262		<i>Catheter site ecchymosis</i>	10052262 Current
Language	<i>Chinese</i>		Code#	
			10052262	
			Language	
			<i>Chinese</i>	
			Current translated term	
			<i>导尿管部位瘀斑</i>	
			Proposed new translation	
			<i>导管部位瘀斑</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter site ecchymosis (Code: 10052262) from 导尿管部位瘀斑 to 导管部位瘀斑 is approved as requested.

CR Number: 2015126008 Implementation Date: 22-May-15 Related CR: 2015126008

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter site hemorrhage</i>	Approved as Requested	English term	
Code#	10052266		<i>Catheter site hemorrhage</i>	10052266 Current
Language	<i>Chinese</i>		Code#	
			10052266	
			Language	
			<i>Chinese</i>	
			Current translated term	
			<i>导尿管部位出血</i>	
			Proposed new translation	
			<i>导管部位出血</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter site hemorrhage (Code: 10052266) from 导尿管部位出血 to 导管部位出血 is approved as requested.

Supplemental Update Report

CR Number: 2015126009 Implementation Date: 22-May-15 Related CR: 2015126009

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter site irritation</i>	Approved as Requested	English term	
Code#	10068003		<i>Catheter site irritation</i>	10068003 Current
Language	<i>Chinese</i>		Code#	
			10068003	
			Language	
			<i>Chinese</i>	
			Current translated term	
			<i>导尿管部位疼痛</i>	
			Proposed new translation	
			<i>导管部位疼痛</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter site irritation (Code: 10068003) from 导尿管部位疼痛 to 导管部位疼痛 is approved as requested.

CR Number: 2015126010 Implementation Date: 22-May-15 Related CR: 2015126010

<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Catheter site redness</i>	Approved as Requested	English term	
Code#	10064622		<i>Catheter site redness</i>	10064622 Current
Language	<i>Chinese</i>		Code#	
			10064622	
			Language	
			<i>Chinese</i>	
			Current translated term	
			<i>导尿管部位发红</i>	
			Proposed new translation	
			<i>导管部位发红</i>	

MSSO Comment: The proposal to rename the Chinese translation of the term Catheter site redness (Code: 10064622) from 导尿管部位发红 to 导管部位发红 is approved as requested.

Supplemental Update Report

CR Number: 2015126011		Implementation Date: 22-May-15	Related CR: 2015126011	
<u>Change Requested</u>	Rename Translated Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
English term	<i>Thrombus in catheter</i>	Approved as Requested	English term	
Code#	10050387		<i>Thrombus in catheter</i>	10050387 Current
Language	Chinese		Code#	
			10050387	
			Language	
			Chinese	
			Current translated term	
			导尿管血栓	
			Proposed new translation	
			导管血栓	

MSSO Comment: The proposal to rename the Chinese translation of the term Thrombus in catheter (Code: 10050387) from 导尿管血栓 to 导管血栓 is approved as requested.

CR Number: 2015127027		Implementation Date: 27-May-15	Related CR: 2015127027	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Methicillin-sensitive S. aureus</i>	Approved Not as Requested After Suspension	Proposed LLT	
			<i>Methicillin-sensitive Staphylococcus aureus infection</i>	10077008 Current
			To PT	
			<i>Staphylococcal infection</i>	10058080

MSSO Comment: The proposal to add a new LLT Methicillin-sensitive S. aureus is approved but not as requested after suspension. Based on subscriber feedback Methicillin-sensitive S. aureus will be rephrased to Methicillin-sensitive Staphylococcus aureus infection to clarify the concept. Methicillin-sensitive Staphylococcus aureus infection will be added as a subconcept LLT under PT Staphylococcal infection.

Supplemental Update Report

CR Number: 2015127034 Implementation Date: 27-May-15 Related CR: 2015127034

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New LLT Proposed LLT <i>NON-ECONOMIC LOSS</i>	Approved Not as Requested After Suspension	Proposed PT <i>Non-economic loss</i>	10077007
		HLT primary <i>Social issues NEC</i>	10070967
		SOC primary <i>Social circumstances</i>	10041244

MSSO Comment: The proposal to add a new LLT NON-ECONOMIC LOSS is approved but not as requested after suspension. NON-ECONOMIC LOSS will be modified to Non-economic loss based on MedDRA capitalization conventions. Non-economic loss is a recognized concept and will be added as a PT under HLT Social issues NEC.

CR Number: 2015135002 Implementation Date: 21-May-15 Related CR: 2015135002

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Promote an LLT Proposed LLT <i>Shock-like symptom</i>	Approved Not as Requested After Suspension	Proposed LLT <i>Shock-like symptom</i>	10040586 Current
From PT <i>Shock</i>		From PT <i>Shock</i>	10040560
HLT primary <i>General signs and symptoms NEC</i>		To PT <i>Shock symptom</i>	10040581

MSSO Comment: The proposal to promote the LLT Shock-like symptom from PT Shock to HLT General signs and symptoms NEC is approved but not as requested after suspension. Rather than promote LLT Shock-like symptom from PT Shock, the MSSO will move LLT Shock-like symptom from PT Shock to the newly promoted PT Shock symptom. Additionally, the non-current LLT Shock symptoms will also be moved under the new PT Shock symptom. In a related change, LLT Shock symptom will be promoted to a PT under HLT Circulatory collapse and shock.

Supplemental Update Report

CR Number: 2015141001 **Implementation Date:** 21-May-15 **Related CR:** 2015135002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Shock symptoms</i>	Approved as Requested	Proposed LLT	
From PT	<i>Shock</i>		<i>Shock symptoms</i>	10040582 Non-Current
To PT	<i>Shock symptom</i>		From PT	
			<i>Shock</i>	10040560
			To PT	
			<i>Shock symptom</i>	10040581

MSSO
Comment:

CR Number: 2015141002 **Implementation Date:** 21-May-15 **Related CR:** 2015135002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT <i>Shock symptom</i>	Approved as Requested	Proposed LLT	
From PT	<i>Shock</i>		<i>Shock symptom</i>	10040581
HLT primary	<i>Circulatory collapse and shock</i>		From PT	
			<i>Shock</i>	10040560
			HLT primary	
			<i>Circulatory collapse and shock</i>	10009193
			SOC primary	
			<i>Vascular disorders</i>	10047065

MSSO
Comment:

CR Number: 2015135003 **Implementation Date:** 27-May-15 **Related CR:** 2015135003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Off label population</i>	Rejected After Suspension		

MSSO
Comment: The proposal to add a new LLT Off label population is not approved after suspension. Please consider LLT Off label use and LLT Drug use in unapproved population for your coding needs. In a related change, a new LLT Product use in unapproved population will be added as a subconcept under PT Product use issue.

Supplemental Update Report

CR Number: 2015147168	Implementation Date: 27-May-15	Related CR: 2015135003		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Product use in unapproved population</i>	Approved as Requested	Proposed LLT	
To PT	<i>Product use issue</i>		<i>Product use in unapproved population</i>	10077011 Current
			To PT	
			<i>Product use issue</i>	10076309

MSSO
Comment:

CR Number: 2015135004	Implementation Date: 27-May-15	Related CR: 2015135004		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Off label indication</i>	Rejected After Suspension		

MSSO
Comment: The proposal to add a new LLT Off label indication is not approved after suspension. Please consider LLT Off label use and LLT Product use in unapproved indication for your coding needs.

CR Number: 2015138017	Implementation Date: 27-May-15	Related CR: 2015138017		
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pseudohypoglycemia</i>	Approved Not as Requested After Suspension	Proposed LLT	
			<i>Pseudohypoglycemia</i>	10077009 Current
			To PT	
			<i>False positive investigation result</i>	10070748

MSSO
Comment: The proposal to add a new PT Pseudohypoglycemia is approved but not as requested after suspension. Pseudohypoglycemia and the British English spelling counterpart spelling Pseudohypoglycaemia will be added as subconcept LLTs under PT False positive investigation result to align with the existing LLT Pseudothrombocytopenia.

Supplemental Update Report

CR Number: 2015147167 Implementation Date: 27-May-15 Related CR: 2015138017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Pseudohypoglycaemia</i>	Approved as Requested	Proposed LLT	
To PT	<i>False positive investigation result</i>		<i>Pseudohypoglycaemia</i>	10077010 Current
			To PT	
			<i>False positive investigation result</i>	10070748

MSSO
Comment:

CR Number: 2015138018 Implementation Date: 21-May-15 Related CR: 2015138018

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Bickerstaff's encephalitis</i>	Approved as Requested	Proposed PT	
			<i>Bickerstaff's encephalitis</i>	10076985
			HLT primary	
			<i>Encephalitis NEC</i>	10014599
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Ocular nerve and muscle disorders</i>	10030059
			SOC secondary	
			<i>Eye disorders</i>	10015919

MSSO
Comment: The proposal to add a new PT Bickerstaff's encephalitis is approved as requested. Bickerstaff's encephalitis is a recognized concept and will be added as a PT under primary HLT Encephalitis NEC; secondary HLTs - HLT Ocular nerve and muscle disorders, HLT Inflammatory disorders following infection and HLT Nervous system autoimmune disorders.

Supplemental Update Report

CR Number: 2015141003	Implementation Date: 21-May-15	Related CR: 2015138018	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	<i>Bickerstaff's encephalitis</i>	Approved as Requested	Proposed PT
To HLT	<i>Inflammatory disorders following infection</i>		<i>Bickerstaff's encephalitis</i>
			To HLT
			<i>Inflammatory disorders following infection</i>
			10076985
			10021982

MSSO
Comment:

CR Number: 2015141004	Implementation Date: 21-May-15	Related CR: 2015138018	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	<i>Bickerstaff's encephalitis</i>	Approved as Requested	Proposed PT
To HLT	<i>Nervous system autoimmune disorders</i>		<i>Bickerstaff's encephalitis</i>
			To HLT
			<i>Nervous system autoimmune disorders</i>
			10076985
			10074484

MSSO
Comment:

CR Number: 2015138019	Implementation Date: 21-May-15	Related CR: 2015138019	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed PT	<i>Pseudogynecomastia</i>	Approved Not as Requested	Proposed LLT
			<i>Pseudogynecomastia</i>
			To PT
			<i>Pseudogynaecomastia</i>
			10076987 Current
			10076986

MSSO
Comment: The proposal to add a new PT Pseudogynecomastia is approved but not as requested. Pseudogynecomastia will be added as the American English spelling LLT under the new PT Pseudogynaecomastia. In a related change, a new PT Pseudogynaecomastia will be added under primary HLT General nutritional disorders NEC; secondary HLT Breast disorders NEC.

Supplemental Update Report

CR Number: 2015141005 Implementation Date: 21-May-15 Related CR: 2015138019

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pseudogynaecomastia</i>	Approved as Requested	Proposed PT	
HLT primary	<i>General nutritional disorders NEC</i>		<i>Pseudogynaecomastia</i>	10076986
SOC primary	<i>Metabolism and nutrition disorders</i>		HLT primary	
			<i>General nutritional disorders NEC</i>	10018067
			SOC primary	
			<i>Metabolism and nutrition disorders</i>	10027433
			HLT secondary	
			<i>Breast disorders NEC</i>	10040675
			SOC secondary	
			<i>Reproductive system and breast disorders</i>	10038604

MSSO
Comment:

CR Number: 2015139001 Implementation Date: 22-May-15 Related CR: 2015139001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>NEUROENDOSCOPY</i>	Approved Not as Requested	Proposed PT	
			<i>Neuroendoscopy</i>	10076990
			HLT primary	
			<i>Skull and brain therapeutic procedures</i>	10040957
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO
Comment: The proposal to add a new LLT NEUROENDOSCOPY is approved but not as requested. NEUROENDOSCOPY will be rephrased to Neuroendoscopy based on MedDRA capitalization conventions. Neuroendoscopy is a recognized surgical procedure and will be added as a PT under HLT Skull and brain therapeutic procedures.

Supplemental Update Report

CR Number: 2015139002 Implementation Date: 22-May-15 Related CR: 2015139002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>EPIGASTRIC DISTURBANCE</i>	Rejected		
To PT	<i>Epigastric discomfort</i>			

MSSO Comment: The proposal to add a new LLT EPIGASTRIC DISTURBANCE to PT Epigastric discomfort is not approved. Epigastric disturbance is a very non-specific concept that could be interpreted in different ways. There are several LLTs in MedDRA, such as LLT Epigastric discomfort, LLT Epigastric fullness or LLT Epigastric irritation which could represent the requested concept.

CR Number: 2015139003 Implementation Date: 22-May-15 Related CR: 2015139003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>SOFT TISSUE SWELLING</i>	Approved Not as Requested	Proposed PT <i>Soft tissue swelling</i>	10076991
			HLT primary <i>Soft tissue disorders NEC</i>	10041288
			SOC primary <i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new LLT SOFT TISSUE SWELLING is approved but not as requested. SOFT TISSUE SWELLING will be rephrased to Soft tissue swelling in accordance with the MedDRA capitalization conventions. Soft tissue swelling is a recognized concept and will be added as a PT under HLT Soft tissue disorders NEC.

CR Number: 2015139004 Implementation Date: 22-May-15 Related CR: 2015139004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Septorhinoplasty</i>	Approved as Requested	Proposed LLT <i>Septorhinoplasty</i>	10076992 Current
			To PT <i>Rhinoplasty</i>	10039099

MSSO Comment: The proposal to add a new LLT Septorhinoplasty is approved as requested. Septorhinoplasty will be added as a subconcept LLT under the broad PT Rhinoplasty.

Supplemental Update Report

CR Number: 2015139005	Implementation Date: 22-May-15	Related CR: 2015139005		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Cyberknife Radiotherapy</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Cyberknife Radiotherapy is not approved. In general, MedDRA does not incorporate trade names in terms. The concept can be represented by existing LLT Stereotactic radiosurgery.

CR Number: 2015139006	Implementation Date: 22-May-15	Related CR: 2015139006		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>High Intensity focused ultrasound</i>	Approved Not as Requested	Proposed PT <i>High intensity focused ultrasound</i>	10076993
			HLT primary <i>Therapeutic procedures NEC</i>	10027700
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new LLT High Intensity focused ultrasound is approved but not as requested. High intensity focused ultrasound is a recognized concept which warrants a PT status because it is a highly specific type of ultrasound therapy. High intensity focused ultrasound will be added as a PT under HLT Therapeutic procedures NEC.

CR Number: 2015139007	Implementation Date: 22-May-15	Related CR: 2015139007		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>TRANSRECTAL ULTRASONOGRAPHY</i>	Approved Not as Requested	Proposed LLT <i>Transrectal ultrasound</i>	10076995 Current
			To PT <i>Ultrasound prostate</i>	10045431

MSSO Comment: The proposal to add a new LLT TRANSRECTAL ULTRASONOGRAPHY is approved but not as requested. TRANSRECTAL ULTRASONOGRAPHY will be renamed to Transrectal ultrasound to be consistent with other MedDRA ultrasound terms and to also follow the MedDRA capitalization conventions. Transrectal ultrasound will be added as a subconcept LLT under PT Ultrasound prostate because the procedure is most frequently used to investigate the prostate gland.

Supplemental Update Report

CR Number: 2015139008 Implementation Date: 22-May-15 Related CR: 2015139008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>LOGOTHERAPY</i>	Approved Not as Requested	Proposed LLT <i>Logotherapy</i>	10076996 Current
			To PT <i>Psychotherapy</i>	10037247

MSSO Comment: The proposal to add a new LLT LOGOTHERAPY is approved but not as requested. LOGOTHERAPY will be rephrased to Logotherapy in accordance with the MedDRA capitalization conventions. Logotherapy will be added as a subconcept LLT under PT Psychotherapy.

CR Number: 2015139009 Implementation Date: 22-May-15 Related CR: 2015139009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Lacunar stroke</i>	Approved Not as Requested	Proposed PT <i>Lacunar stroke</i>	10076994
			HLT primary <i>Central nervous system haemorrhages and cerebrovascular accidents</i>	10007948
			SOC primary <i>Nervous system disorders</i>	10029205
			HLT secondary <i>Cerebrovascular and spinal necrosis and vascular insufficiency</i>	10008192
			SOC secondary <i>Vascular disorders</i>	10047065

MSSO Comment: The proposal to add a new LLT Lacunar stroke is approved but not as requested. Lacunar stroke is a distinct concept and will be added as a PT under primary HLT Central nervous system haemorrhages and cerebrovascular accidents; secondary HLT Cerebrovascular and spinal necrosis and vascular insufficiency. In MedDRA "stroke" and "infarction" terms are placed at the PT level as "stroke" terms represent the clinical aspect whereas the "infarction" terms represent the pathologic concepts.

Supplemental Update Report

CR Number: 2015139010	Implementation Date: 22-May-15	Related CR: 2015139010	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	BLADDER ELECTROCAUTERIZATION	Approved Not as Requested	Proposed LLT <i>Bladder electrocauterization</i>
			10076997 Current
			To PT <i>Transurethral bladder resection</i>
			10052693

MSSO
Comment: The proposal to add a new LLT BLADDER ELECTROCAUTERIZATION is approved but not as requested. BLADDER ELECTROCAUTERIZATION will be rephrased to Bladder electrocauterization in accordance with the MedDRA capitalization conventions. Bladder electrocauterization and the British English spelling counterpart Bladder electrocauterisation will be added as subconcept LLTs under PT Transurethral bladder resection. In a related change, PT Diathermy of bladder tumour will be demoted as a subconcept LLT under PT Transurethral bladder resection. Furthermore, LLT Transurethral resection of bladder tumor, LLT Transurethral resection of bladder tumour and LLT TURBT will be moved from PT Bladder neoplasm surgery to PT Transurethral bladder resection.

CR Number: 2015142006	Implementation Date: 22-May-15	Related CR: 2015139010	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Bladder electrocauterisation</i>	Approved as Requested	Proposed LLT <i>Bladder electrocauterisation</i>
To PT	<i>Transurethral bladder resection</i>		10076998 Current
			To PT <i>Transurethral bladder resection</i>
			10052693

MSSO
Comment:

CR Number: 2015142007	Implementation Date: 22-May-15	Related CR: 2015139010	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>
PT to merge	<i>Diathermy of bladder tumour</i>	Approved as Requested	PT to merge <i>Diathermy of bladder tumour</i>
To PT	<i>Transurethral bladder resection</i>		10012763 Current
			To PT <i>Transurethral bladder resection</i>
			10052693

MSSO
Comment:

Supplemental Update Report

CR Number: 2015142008 Implementation Date: 22-May-15 Related CR: 2015139010

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Transurethral resection of bladder tumor</i>	Approved as Requested	Proposed LLT	
From PT	<i>Bladder neoplasm surgery</i>		<i>Transurethral resection of bladder tumor</i>	10071280 Current
To PT	<i>Transurethral bladder resection</i>		From PT	
			<i>Bladder neoplasm surgery</i>	10064272
			To PT	
			<i>Transurethral bladder resection</i>	10052693

MSSO
Comment:

CR Number: 2015142009 Implementation Date: 22-May-15 Related CR: 2015139010

<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Transurethral resection of bladder tumour</i>	Approved as Requested	Proposed LLT	
From PT	<i>Bladder neoplasm surgery</i>		<i>Transurethral resection of bladder tumour</i>	10071277 Current
To PT	<i>Transurethral bladder resection</i>		From PT	
			<i>Bladder neoplasm surgery</i>	10064272
			To PT	
			<i>Transurethral bladder resection</i>	10052693

MSSO
Comment:

Supplemental Update Report

CR Number: 2015142010 Implementation Date: 22-May-15 Related CR: 2015139010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	TURBT	Approved as Requested	Proposed LLT	
From PT	Bladder neoplasm surgery		TURBT	10071281 Current
To PT	Transurethral bladder resection		From PT	
			Bladder neoplasm surgery	10064272
			To PT	
			Transurethral bladder resection	10052693

MSSO
Comment:

CR Number: 2015139011 Implementation Date: 22-May-15 Related CR: 2015139011

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Bezold–Jarisch reflex	Approved as Requested	Proposed PT	
			Bezold-Jarisch reflex	10076999
			HLT primary	
			Rate and rhythm disorders NEC	10037908
			SOC primary	
			Cardiac disorders	10007541
		HLT secondary		
		Vascular hypertensive disorders NEC	10020774	
		SOC secondary		
		Vascular disorders	10047065	

MSSO The proposal to add a new term Bezold–Jarisch reflex is approved as requested. Bezold–Jarisch reflex is a recognized concept and will be added as a PT under primary
Comment: HLT Rate and rhythm disorders NEC; secondary HLTs - HLT Vascular hypertensive disorders NEC and HLT Neurological signs and symptoms NEC.

Supplemental Update Report

CR Number: 2015142011		Implementation Date: 22-May-15	Related CR: 2015139011	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Bezold-Jarisch reflex</i>	Approved as Requested	Proposed PT <i>Bezold-Jarisch reflex</i>	10076999
To HLT	<i>Neurological signs and symptoms NEC</i>		To HLT <i>Neurological signs and symptoms NEC</i>	10029306

MSSO
Comment:

CR Number: 2015139012		Implementation Date: 22-May-15	Related CR: 2015139012	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Link (move) an LLT to another PT <i>Fistula of small intestine</i>	Approved Not as Requested	Proposed PT <i>Ileal fistula</i>	10065728 Current
From PT	<i>Ileal fistula</i>		With LLT <i>Fistula of small intestine</i>	10065850
To PT	<i>Intestinal fistula</i>			

MSSO
Comment: The proposal to move the LLT Fistula of small intestine from PT Ileal fistula to PT Intestinal fistula is approved but not as requested. Rather than move LLT Fistula of small intestine to PT Intestinal fistula, the MSSO will switch the broader LLT Fistula of small intestine with PT Ileal fistula. Furthermore, to reduce over-granularity at the PT level, PT Duodenal fistula and PT Jejunal fistula will be merged under the newly promoted PT Fistula of small intestine to have all anatomical subconcepts as LLTs.

CR Number: 2015142012		Implementation Date: 22-May-15	Related CR: 2015139012	
<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Duodenal fistula</i>	Approved as Requested	PT to merge <i>Duodenal fistula</i>	10013828 Current
To PT	<i>Fistula of small intestine</i>		To PT <i>Fistula of small intestine</i>	10065850

MSSO
Comment:

Supplemental Update Report

CR Number: 2015142013	Implementation Date: 22-May-15	Related CR: 2015139012	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>
			<u>MedDRA Code #</u>
PT to merge	<i>Jejunal fistula</i>	Approved as Requested	PT to merge
To PT	<i>Fistula of small intestine</i>		<i>Jejunal fistula</i>
			10065719 Current
			To PT
			<i>Fistula of small intestine</i>
			10065850

MSSO
Comment:

CR Number: 2015139013	Implementation Date: 22-May-15	Related CR: 2015139013	
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>
			<u>MedDRA Code #</u>
Proposed LLT	<i>Colour vision change</i>	Approved as Requested	Proposed LLT
From PT	<i>Colour blindness acquired</i>		<i>Colour vision change</i>
To PT	<i>Visual impairment</i>		10068918 Current
			From PT
			<i>Colour blindness acquired</i>
			10010051
			To PT
			<i>Visual impairment</i>
			10047571

MSSO
Comment: The proposal to move the LLT Colour vision change from PT Colour blindness acquired to PT Visual impairment is approved as requested. The specific wording of LLT Colour vision change and its American English counterpart LLT Color vision change does not clearly relate to color blindness or chromatopsia. Therefore, the move to the broad PT Visual impairment is appropriate.

CR Number: 2015142014	Implementation Date: 22-May-15	Related CR: 2015139013	
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>
			<u>MedDRA Code #</u>
Proposed LLT	<i>Color vision change</i>	Approved as Requested	Proposed LLT
From PT	<i>Colour blindness acquired</i>		<i>Color vision change</i>
To PT	<i>Visual impairment</i>		10068914 Current
			From PT
			<i>Colour blindness acquired</i>
			10010051
			To PT
			<i>Visual impairment</i>
			10047571

MSSO
Comment:

Supplemental Update Report

CR Number: 2015139014 Implementation Date: 22-May-15 Related CR: 2015139014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>HYPERTENSIVE CEREBROVASCULAR DISEASE</i>	Approved Not as Requested	Proposed PT <i>Hypertensive cerebrovascular disease</i>	10077000
HLT primary	<i>Central nervous system vascular disorders NEC</i>		HLT primary <i>Central nervous system vascular disorders NEC</i>	10007962
SOC primary	<i>Nervous system disorders</i>		SOC primary <i>Nervous system disorders</i>	10029205
			HLT secondary <i>Hypertension complications</i>	10010164
			SOC secondary <i>Vascular disorders</i>	10047065

MSSO Comment: The proposal to add a new PT HYPERTENSIVE CEREBROVASCULAR DISEASE to primary HLT Central nervous system vascular disorders NEC; secondary HLT Hypertension complications is approved but not as requested. HYPERTENSIVE CEREBROVASCULAR DISEASE will be rephrased to Hypertensive cerebrovascular disease in accordance with the MedDRA capitalization conventions.

CR Number: 2015139015 Implementation Date: 22-May-15 Related CR: 2015139015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Osteoporotic fracture</i>	Approved as Requested	Proposed PT <i>Osteoporotic fracture</i>	10031290
To HLT	<i>Bone metabolism disorders</i>		To HLT <i>Bone metabolism disorders</i>	10005992

MSSO Comment: The proposal to link the PT Osteoporotic fracture to the HLT Bone metabolism disorders is approved as requested. Proposed secondary HLT Bone metabolism disorders is relevant to the etiology of the PT term concept Osteoporotic fracture.

Supplemental Update Report

CR Number: 2015139016 Implementation Date: 22-May-15 Related CR: 2015139016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	DYSPHONIA CLERICORUM	Approved Not as Requested	Proposed LLT	
To PT	Pharyngeal inflammation		Dysphonia clericorum	10077001 Current
			To PT	
			Dysphonia	10013952

MSSO Comment: The proposal to add a new LLT DYSPHONIA CLERICORUM to PT Pharyngeal inflammation is approved but not as requested. DYSPHONIA CLERICORUM will be rephrased to Dysphonia clericorum in accordance with the MedDRA capitalization conventions and placed as a subconcept LLT under PT Dysphonia.

CR Number: 2015139017 Implementation Date: 22-May-15 Related CR: 2015139017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Clergyman's sore throat	Approved Not as Requested	Proposed LLT	
To PT	Pharyngeal inflammation		Clergyman's sore throat	10077002 Current
			To PT	
			Dysphonia	10013952

MSSO Comment: The proposal to add a new LLT Clergyman's sore throat to PT Pharyngeal inflammation is approved but not as requested. Clergyman's sore throat is a recognized colloquial synonym of dysphonia clericorum and added as an LLT under PT Dysphonia.

Supplemental Update Report

CR Number: 2015140001 Implementation Date: 22-May-15 Related CR: 2015140001

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Multinucleate cell angiohistiocytoma</i>	Approved as Requested	Proposed PT <i>Multinucleate cell angiohistiocytoma</i>	10077003
		HLT primary <i>Skin neoplasms benign</i>	10040898
		SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
		HLT secondary <i>Skin neoplasms benign</i>	10040898
		SOC secondary <i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO Comment: The proposal to add a new term Multinucleate cell angiohistiocytoma is approved as requested. Multinucleate cell angiohistiocytoma is a recognized concept and will be added as a PT under multi-axial HLT Skin neoplasms benign (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps); secondary SOC Skin and subcutaneous tissue disorders). In a related change, PT Multinucleate cell angiohistiocytoma will be linked to HLT Vascular neoplasms.

CR Number: 2015142015 Implementation Date: 22-May-15 Related CR: 2015140001

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT <i>Multinucleate cell angiohistiocytoma</i>	Approved as Requested	Proposed PT <i>Multinucleate cell angiohistiocytoma</i>	10077003
To HLT <i>Vascular neoplasms</i>		To HLT <i>Vascular neoplasms</i>	10057189

MSSO Comment:

Supplemental Update Report

CR Number: 2015140002 **Implementation Date:** 22-May-15 **Related CR:** 2015140002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Round atelectasis</i>	Approved as Requested	Proposed LLT <i>Round atelectasis</i>	10077004 Current
			To PT <i>Atelectasis</i>	10003598

MSSO Comment: The proposal to add a new term Round atelectasis is approved as requested. Round atelectasis, a form of non-segmental atelectasis will be placed as a subconcept LLT under PT Atelectasis.

CR Number: 2015140005 **Implementation Date:** 26-May-15 **Related CR:** 2015140005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Pleuritic discomfort</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Pleuritic discomfort is not approved. The concept can be represented by LLT Chest discomfort or LLT Pleuritic pain.

CR Number: 2015140007 **Implementation Date:** 27-May-15 **Related CR:** 2015140007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Antibiotic-associated diarrhoea</i>	Rejected		
From PT	<i>Diarrhoea</i>			

MSSO Comment: The proposal to promote the LLT Antibiotic-associated diarrhoea from PT Diarrhoea is not approved. Although the MSSO refrains from adding new terms that exhibit cause and effect relationships such as "drug induced" terms, existing LLT Antibiotic-associated diarrhea is appropriately placed as a subconcept under PT Diarrhoea since drug-induced concepts are generally placed as LLTs under broad concept PTs.

Supplemental Update Report

CR Number: 2015141026 Implementation Date: 27-May-15 Related CR: 2015141026

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Asthma- chronic obstructive pulmonary disease overlap syndrome</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Bronchospasm and obstruction</i>		<i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>	10077005
SOC primary	<i>Respiratory, thoracic and mediastinal disorders</i>		HLT primary	
			<i>Bronchospasm and obstruction</i>	10006484
			SOC primary	
			<i>Respiratory, thoracic and mediastinal disorders</i>	10038738
			HLT secondary	
			<i>Allergic conditions NEC</i>	10027654
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new PT Asthma- chronic obstructive pulmonary disease overlap syndrome to primary HLT Bronchospasm and obstruction primary SOC Respiratory, thoracic and mediastinal disorders is approved but not as requested. The extra space after the hyphen will be removed. Asthma-chronic obstructive pulmonary disease overlap syndrome is a recognized concept and will be added as a PT with secondary mapping to HLT Allergic conditions NEC. In related changes, existing LLTs - LLT Chronic obstructive asthma (with obstructive pulmonary disease), w/o ment of status asthmaticus, LLT Chronic obstructive asthma (with obstructive pulmonary disease), w/o-ment of status asthmaticus and LLT Chronic obstructive asthma (with obstructive pulmonary disease) will be moved from PT Asthma to the new PT Asthma-chronic obstructive pulmonary disease overlap syndrome. Furthermore, Asthma-COPD overlap syndrome will be added as an acronym LLT under PT Asthma-chronic obstructive pulmonary disease overlap syndrome.

CR Number: 2015147163 Implementation Date: 27-May-15 Related CR: 2015141026

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Chronic obstructive asthma (with obstructive pulmonary disease), w/o ment of status asthmaticus</i>	Approved as Requested	Proposed LLT	
From PT	<i>Asthma</i>		<i>Chronic obstructive asthma (with obstructive pulmonary disease), w/o ment of status asthmaticus</i>	10009030 Non-Current
To PT	<i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>		From PT	
			<i>Asthma</i>	10003553
			To PT	
			<i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>	10077005

MSSO Comment:

Supplemental Update Report

CR Number: 2015147164

Implementation Date: 27-May-15

Related CR: 2015141026

Change Requested

Link (move) an LLT to another PT

Final Disposition

Final Placement

MedDRA Code #

Proposed LLT	<i>Chronic obstructive asthma (with obstructive pulmonary disease), w/o-ment of status asthmaticus</i>	Approved as Requested	Proposed LLT <i>Chronic obstructive asthma (with obstructive pulmonary disease), w/o-ment of status asthmaticus</i>	10009029 Non-Current
From PT	<i>Asthma</i>		From PT <i>Asthma</i>	10003553
To PT	<i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>		To PT <i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>	10077005

MSSO

Comment:

CR Number: 2015147165

Implementation Date: 27-May-15

Related CR: 2015141026

Change Requested

Link (move) an LLT to another PT

Final Disposition

Final Placement

MedDRA Code #

Proposed LLT	<i>Chronic obstructive asthma (with obstructive pulmonary disease)</i>	Approved as Requested	Proposed LLT <i>Chronic obstructive asthma (with obstructive pulmonary disease)</i>	10009028 Current
From PT	<i>Asthma</i>		From PT <i>Asthma</i>	10003553
To PT	<i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>		To PT <i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>	10077005

MSSO

Comment:

Supplemental Update Report

CR Number: 2015147166

Implementation Date: 27-May-15

Related CR: 2015141026

Change Requested

Add a New LLT

Final Disposition

Final Placement

MedDRA
Code #

Proposed LLT	<i>Asthma-COPD overlap syndrome</i>	Approved as Requested	Proposed LLT	
To PT	<i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>		<i>Asthma-COPD overlap syndrome</i>	10077006 Current
			To PT	
			<i>Asthma-chronic obstructive pulmonary disease overlap syndrome</i>	10077005

MSSO

Comment:
