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Site Number

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Subject Number

### Prior Crohn's Disease Medication Class- Biologics

What is the category for the medication?		CMCAT CMCAT
For what indication was the medication taken?		CMINDC CMINDC
What is the subcategory for the medication?		CMSCAT CMSCAT
What was the medication identifier?		CMSPID CMSPID; FASPID; MHLNKID
What was the name of the biologic drug taken for Crohn's disease?	CMTRT CMTRT	
What was the start date of this biologic? (DD-MMM-YYYY)		CMSTDAT CMSTDTTC
What was the end date of this biologic? (DD-MMM-YYYY)		CMENDAT CMENDTTC
How many months did the subject take this biologic?	CMDUR CMDUR	
What was the maximum dose amount of this biologic?	MXDOSAMT_FAORRES FAORRES where FATEST = "Maximum Dose Amount"	
What was the unit of the maximum dose amount of this biologic?	MXDOSAMT_FAORRESU FAORRESU where FATEST = "Maximum Dose Amount"	
What was the frequency of the maximum dose amount of this biologic?	MXDOSFRQ_FAORRES FAORRES where FATEST = "Frequency of Maximum Dose Amount"	
What was the final dose amount of this biologic?	FNDOSAMT_FAORRES FAORRES where FATEST = "Final Dose Amount"	



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What was the final dose amount unit of this biologic?	<p><b>FNDOAMT_FAORRESU</b>  <b>FAORRESU where FATEST = "Final Dose Amount"</b></p>
What was the frequency of the final dose amount of this biologic?	<p><b>FNDOFRQ_FAORRES</b>  <b>FAORRES where FATEST = "Frequency of Final Dose Amount"</b></p>
What was the route of administration of this biologic?	<p><b>CMROUTE</b>  <b>CMROUTE</b></p>
What was the primary reason for discontinuation of this biologic?	<p><b>CMRSDISC</b>  <b>CMRSDISC</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> Primary non-responder</li> <li><input type="radio"/> Secondary non-responder</li> <li><input type="radio"/> Intolerance</li> <li><input type="radio"/> Completed induction phase</li> <li><input type="radio"/> Treatment complete</li> <li><input type="radio"/> Loss of insurance</li> <li><input type="radio"/> Cost</li> <li><input type="radio"/> Treatment no longer indicated</li> <li><input type="radio"/> Other</li> <li><input type="radio"/> Unknown</li> </ul>
If primary non-responder, what were the signs and symptoms leading to discontinuation of treatment? <i>Check all that apply.</i>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Lack of improvement or worsening of stool frequency</li> <li><input type="checkbox"/> Lack of improvement or worsening of abdominal pain</li> <li><input type="checkbox"/> Lack of improvement or worsening of Crohn's disease related fever</li> <li><input type="checkbox"/> Lack of improvement or worsening of draining fistula or development of new fistula</li> <li><input type="checkbox"/> Lack of improvement or worsening of rectal bleeding</li> <li><input type="checkbox"/> Initiation or increased dosage of antidiarrheal medication</li> <li><input type="checkbox"/> Lack of improvement or worsening in the endoscopic appearance of the colonic mucosa</li> <li><input type="checkbox"/> Other</li> </ul> <p><b>PRSSDISC(n)_FAORRES</b>  <b>If not "Other" then FAORRES where FATESTCD = "SSDISC" AND FAOBJ = CMTRT</b></p>
If "Other", specify.	<p><b>PROSSDISC(n)_FAORRES</b>  <b>FAORRES where FATESTCD = "SSDISC" and FAOBJ = CMTRT</b></p>



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<p>If secondary non-responder, what were the signs and symptoms leading to treatment discontinuation? <i>Check all that apply.</i></p>	<input type="checkbox"/> Worsening of stool frequency <input type="checkbox"/> Worsening of abdominal pain <input type="checkbox"/> Occurrence or worsening of Crohn's disease related fever <input type="checkbox"/> Worsening of draining fistula or development of new fistula <input type="checkbox"/> Worsening of rectal bleeding <input type="checkbox"/> Antidiarrheal medication required <input type="checkbox"/> Worsening in the endoscopic appearance of the colonic mucosa <input type="checkbox"/> Other	<p>SCSSDISC(n)_FAORRES</p> <p>If not "Other" then FAORRES where FATESTCD = "SSDISC" and FAOBJ = CMTRT</p>
<p>If "Other", specify.</p>		<p>SCOSSDISC(n)_FAORRES</p> <p>FAORRES where FATESTCD = "SSDISC" and FAOBJ = CMTRT</p>
<p>What was the category of the medical history?</p>		<p>MHCAT</p> <p>MHCAT</p>
<p>When did the medical history event start relative to the study reference period?</p>		<p>MHSTRF</p> <p>MHSTRF</p>
<p>What was the relationship to the non-study medication?</p>		<p>MHRELSNT</p> <p>MHRELSNT</p>
<p>If treatment was discontinued due to intolerance, what was the condition indicating intolerance? <i>Check all that apply.</i></p>	<input type="checkbox"/> Serious infection <input type="checkbox"/> Hepatotoxicity <input type="checkbox"/> Hypersensitivity <input type="checkbox"/> Demyelinating disease <input type="checkbox"/> Lupus-like syndrome <input type="checkbox"/> Significant injection site reactions <input type="checkbox"/> Significant acute administration reactions <input type="checkbox"/> Significant delayed administration reactions	<p>INTCOND(n)_MHTERM</p> <p>MHTERM; MHGRPID is assigned according to selection</p>
<p>What was the subcategory of the medical history?</p>		<p>SISRSS_MHSCAT</p> <p>MHSCAT</p>
<p>What is the observation group identifier?</p>		<p>SISRSS_MHGRPID</p> <p>MHGRPID</p>



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<p>If significant injection site reactions, what were the specific signs and symptoms causing treatment intolerance? <i>Check all that apply.</i></p>	<p><input type="checkbox"/> Significant bruising <span style="float: right;">SISRSS(n)_MHTERM</span>  <input type="checkbox"/> Erythema <span style="float: right; color: red;">MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT INJECTION SITE REACTIONS"</span>  <input type="checkbox"/> Hemorrhage</p>
<p>What was the subcategory of the medical history?</p>	<p style="text-align: right;"><span style="background-color: #cccccc;">SAARSS_MHSCAT</span> <span style="background-color: red; color: white;">MHSCAT</span></p>
<p>What is the observation group identifier?</p>	<p style="text-align: right;"><span style="background-color: #cccccc;">SAARSS_MHGRPID</span> <span style="background-color: red; color: white;">MHGRPID</span></p>
<p>If significant acute administration reactions, what were the specific signs and symptoms causing treatment intolerance? <i>Check all that apply.</i></p>	<p><input type="checkbox"/> Fever greater <span style="float: right;">SAARSS(n)_MHTERM; C</span>  <input type="checkbox"/> Chills or rigors <span style="float: right; color: red;">MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT ACUTE ADMINISTRATION REACTIONS"</span>  <input type="checkbox"/> Itching  <input type="checkbox"/> Rash  <input type="checkbox"/> Flushing  <input type="checkbox"/> Urticaria or angioedema  <input type="checkbox"/> Breathing difficulties  <input type="checkbox"/> Clinical hypotension</p>
<p>What was the subcategory of the medical history?</p>	<p style="text-align: right;"><span style="background-color: #cccccc;">SDARSS_MHSCAT</span> <span style="background-color: red; color: white;">MHSCAT</span></p>
<p>What is the observation group identifier?</p>	<p style="text-align: right;"><span style="background-color: #cccccc;">SDARSS_MHGRPID</span> <span style="background-color: red; color: white;">MHGRPID</span></p>
<p>If significant delayed administration reactions, what were the signs and symptoms causing treatment intolerance? <i>Check all that apply.</i></p>	<p><input type="checkbox"/> Myalgias <span style="float: right;">SDARSS(n)_MHTERM</span>  <input type="checkbox"/> Arthralgias <span style="float: right; color: red;">If not "Other symptom" then MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT DELAYED ADMINISTRATION"</span>  <input type="checkbox"/> Malaise  <input type="checkbox"/> Rash  <input type="checkbox"/> Fever  <input type="checkbox"/> Other symptom</p>

	<table border="1"> <tr> <td data-bbox="656 210 732 285"></td> <td data-bbox="732 210 808 285"></td> <td data-bbox="808 210 885 285"></td> </tr> <tr> <td colspan="3" data-bbox="711 285 829 306">Site Number</td> </tr> <tr> <td data-bbox="956 210 1032 285"></td> <td data-bbox="1032 210 1109 285"></td> <td data-bbox="1109 210 1185 285"></td> <td data-bbox="1185 210 1261 285"></td> <td data-bbox="1261 210 1338 285"></td> </tr> <tr> <td colspan="5" data-bbox="1068 285 1219 306">Subject Number</td> </tr> </table>				Site Number								Subject Number				
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Prior Crohn's Disease Medication Class- Biologics			
If "Other symptom", specify.	<table border="1"> <tr> <td data-bbox="829 495 1101 516">SDARSS(n)_MHTERMOTH</td> </tr> <tr> <td data-bbox="829 522 1503 567">MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT DELAYED ADMINISTRATION REACTIONS"</td> </tr> </table>	SDARSS(n)_MHTERMOTH	MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT DELAYED ADMINISTRATION REACTIONS"
SDARSS(n)_MHTERMOTH			
MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT DELAYED ADMINISTRATION REACTIONS"			