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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)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> CMSTDAT CMSTDTC										
What was the end date of this biologic? (DD-MMM-YYYY)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> CMENDAT CMENDTC										
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?	<div>FNDOSAMT_FAORRESU</div> <div>FAORRESU where FATEST = "Final Dose Amount"</div>
What was the frequency of the final dose amount of this biologic?	<div>FNDOSFRQ_FAORRES</div> <div>FAORRES where FATEST = "Frequency of Final Dose Amount"</div>
What was the route of administration of this biologic?	<div>CMROUTE</div> <div>CMROUTE</div>
What was the primary reason for discontinuation of this biologic?	<div>CMRSDISC</div> <div>CMRSDISC</div> <div> <input type="radio"/> Primary non-responder <input type="radio"/> Secondary non-responder <input type="radio"/> Intolerance <input type="radio"/> Completed induction phase <input type="radio"/> Treatment complete <input type="radio"/> Loss of insurance <input type="radio"/> Cost <input type="radio"/> Treatment no longer indicated <input type="radio"/> Other <input type="radio"/> Unknown </div>
If primary non-responder, what were the signs and symptoms leading to discontinuation of treatment? <i>Check all that apply.</i>	<div> <input type="checkbox"/> Lack of improvement or worsening of stool frequency <input type="checkbox"/> Lack of improvement or worsening of abdominal pain <input type="checkbox"/> Lack of improvement or worsening of Crohn's disease related fever <input type="checkbox"/> Lack of improvement or worsening of draining fistula or development of new fistula <input type="checkbox"/> Lack of improvement or worsening of rectal bleeding <input type="checkbox"/> Initiation or increased dosage of antidiarrheal medication <input type="checkbox"/> Lack of improvement or worsening in the endoscopic appearance of the colonic mucosa <input type="checkbox"/> Other </div> <div> <div>PRSSDISC(n)_FAORRES</div> <div>If not "Other" then FAORRES where FATESTCD = "SSDISC" AND FAOBJ = CMTRT</div> </div>
If "Other", specify.	<div>PROSSDISC(n)_FAORRES</div> <div>FAORRES where FATESTCD = "SSDISC" and FAOBJ = CMTRT</div>



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If secondary non-responder, what were the signs and symptoms leading to treatment discontinuation?
Check all that apply.

- ☐ Worsening of stool frequency
- ☐ Worsening of abdominal pain
- ☐ Occurrence or worsening of Crohn's disease related fever
- ☐ Worsening of draining fistula or development of new fistula
- ☐ Worsening of rectal bleeding
- ☐ Antidiarrheal medication required
- ☐ Worsening in the endoscopic appearance of the colonic mucosa
- ☐ Other

SCSSDISC(n)_FAORRES

If not "Other" then FAORRES where FATESTCD = "SSDISC" and FAOBJ = CMTRT

If "Other", specify.

SCSSDISC(n)_FAORRES

FAORRES where FATESTCD = "SSDISC" and FAOBJ = CMTRT

What was the category of the medical history?

MHCAT

MHCAT

When did the medical history event start relative to the study reference period?

MHSTRF

MHSTRF

What was the relationship to the non-study medication?

MHRELSNT

MHRELSNT

If treatment was discontinued due to intolerance, what was the condition indicating intolerance?
Check all that apply.

- ☐ Serious infection
- ☐ Hepatotoxicity
- ☐ Hypersensitivity
- ☐ Demyelinating disease
- ☐ Lupus-like syndrome
- ☐ Significant injection site reactions
- ☐ Significant acute administration reactions
- ☐ Significant delayed administration reactions

INTCOND(n)_MHTERM

MHTERM; MHGRPID is assigned according to selection

What was the subcategory of the medical history?

SISRSS_MHSCAT

MHSCAT

What is the observation group identifier?

SISRSS_MHGRPID

MHGRPID



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If significant injection site reactions, what were the specific signs and symptoms causing treatment intolerance?

Check all that apply.

- ☐ Significant bruising
☐ Erythema
☐ Hemorrhage

SISRSS(n)_MHTERM

MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT INJECTION SITE REACTIONS"

What was the subcategory of the medical history?

SAARSS_MHSCAT

MHSCAT

What is the observation group identifier?

SAARSS_MHGRPID

MHGRPID

If significant acute administration reactions, what were the specific signs and symptoms causing treatment intolerance?

Check all that apply.

- ☐ Fever greater
☐ Chills or rigors
☐ Itching
☐ Rash
☐ Flushing
☐ Urticaria or angioedema
☐ Breathing difficulties
☐ Clinical hypotension

SAARSS(n)_MHTERM } C

MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT ACUTE ADMINISTRATION REACTIONS"

What was the subcategory of the medical history?

SDARSS_MHSCAT

MHSCAT

What is the observation group identifier?

SDARSS_MHGRPID

MHGRPID


If significant delayed administration reactions, what were the signs and symptoms causing treatment intolerance?

Check all that apply.

- ☐ Myalgias
☐ Arthralgias
☐ Malaise
☐ Rash
☐ Fever
☐ Other symptom

SDARSS(n)_MHTERM

If not "Other symptom" then MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT DELAYED ADMINISTRATION"

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	Site Number	Subject Number

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If "Other symptom", specify.	<div>SDARSS(n)_MHTERMOTH</div> <div>MHTERM where MHSCAT = "SIGN/SYMPTOMS OF SIGNIFICANT DELAYED ADMINISTRATION REACTIONS"</div>