Prior Crohn's Disease Medication Class- Immunomodulators

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 immunomodulator drug taken for Crohn's disease?	CMTRT CMTRT
What was the start date of this immunomodulator? (DD-MMM-YYYY)	CMSTDAT CMSTDTC
What was the end date of this immunomodulator? (DD-MMM-YYYY)	CMENDAT CMENDTC
How many months did the subject take this immunomodulator?	CMDUR CMDUR
What was the maximum dose amount of this immunomodulator?	MXDOSAMT_FAORRES FAORRES where FATEST = "Maximum Dose Amount"
What was the unit of the maximum dose amount of this immunomodulator?	MXDOSAMT_FAORRESU FAORRESU where FATEST = "Maximum Dose Amount"
What was the frequency of the maximum dose amount of this immunomodulator?	MXDOSFRQ_FAORRES FAORRES where FATEST = "Frequency of Maximum Dose Amount"

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What was the final dose amount of this immunomodulator?	**FNDOSAMT_FAORRES** **FAORRES where FATEST = "Final Dose Amount"**
What was the final dose amount unit of this immunomodulator?	**FNDOSAMT_FAORRESU** **FAORRESU where FATEST = "Final Dose Amount"**
What was the frequency of the final dose amount of this immunomodulator?	**FNDOSFRQ_FAORRES** **FAORRES where FATEST = "Frequency of Final Dose Amount"**
What was the route of administration of this immunomodulator?	**CMROUTE** **CMROUTE**
What was the primary reason for discontinuation of this immunomodulator?	○ Non-response **CMRSDISC** **CMRSDISC** ○ Intolerance ○ Loss of insurance ○ Cost ○ Treatment no longer indicated ○ Other ○ Unknown
If "Non-response", was the subject receiving a treatment regimen for this immunomodulator which, according to protocol-defined criteria, was expected to be efficacious?	○ No **EXETRIND_FAORRES** **FAORRES where FATESTCD = "EXETRIND" AND FAOBJ = CMTRT** ○ Yes

Site Number   Subject Number

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If "Non-response", what were the signs and symptoms leading to discontinuation of treatment? *Check all that apply.*	☐ Lack of improvement or worsening of stool frequency ☐ Lack of improvement or worsening of abdominal pain ☐ Lack of improvement or worsening of Crohn's disease related fever ☐ Lack of improvement or worsening of draining fistula or development of new fistula ☐ Lack of improvement or worsening of rectal bleeding ☐ Initiation or increased dosage of antidiarrheal medication ☐ Other **SSDISC(n)_FAORRES** **FAORRES where FATESTCD = "SSDISC" AND FAOBJ = CMTRT**
If "Other", specify.	**OSSDISC(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 ☐ Pancreatitis ☐ Leukopenia ☐ Thrombocytopenia ☐ Other **INTCOND(n)_MHTERM** **If not "Other" then MHTERM**
If "Other", what was the other condition indicating intolerance to previous immunomodulator treatment?	**INTCOND(n)_MHTERMOTH** **MHTERM**