Prior Crohn's Disease Medications - High Level Only

What is the category for the medication?		**CMCAT** **CMCAT**
For what indication was the medication taken?		**CMINDC** **CMINDC**
Was the medication prespecified?		**CMPRESP** **CMPRESP**
What is the subcategory for the medication?		**BIOLGC_CMSCAT** **CMSCAT;CMTRT**
Did the subject previously take any biologic medications to treat Crohn's disease?	◯ No ◯ Yes	**BIOLGC_CMOCCUR** **CMOCCUR where CMTRT and CMSCAT="BIOLOGICS"**
Did the subject discontinue any biologic medications previously taken to treat Crohn's disease, prior to the baseline visit?	◯ No ◯ Yes	**BIOLGC_CMDISC** **[NOT SUBMITTED]**
Were any biologic medications taken to treat Crohn's disease ongoing as of the baseline visit?	◯ No ◯ Yes	**BIOLGC_CMONGO** **[NOT SUBMITTED]**
What is the subcategory for the medication?		**IMMUNLTR_CMSCAT** **CMSCAT;CMTRT**
What was the observation identifier?		**IMMUNLTR_CMLNKID** **CMLNKID; MHLNKID**
Did the subject previously take any immunomodulator medications to treat Crohn's disease?	◯ No ◯ Yes	**IMMUNLTR_CMOCCUR** **CMOCCUR where CMTRT and CMSCAT="IMMUNOMODULATORS"**

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Did the subject discontinue any immunomodulator medications to treat Crohn's disease, prior to the baseline visit?	○ No ○ Yes IMMUNLTR_CMDISC [NOT SUBMITTED]
Were any immunomodulator medications used to treat Crohn's disease ongoing as of the baseline visit?	○ No ○ Yes IMMUNLTR_CMONGO [NOT SUBMITTED]
Were contraindications to immunomodulators the reason for not using immunomodulators to treat Crohn's disease?	○ No ○ Yes IMMUNLTR_CMCREASOC NSCM.CMREASOC
If Yes, what were the contraindications to immunomodulator treatments? *Check all that apply.*	☐ Pre-existing medical condition ☐ Clinically significant adverse reaction to previous immunomodulator treatment IMMUNLTR(n)_CMCSCITYP [NOT SUBMITTED]
What is the identifier for the pre-existing medical condition?	IMMUNLTR(n)_CMMHNO Associate with related MH record via RELREC
What was the category of the medical history?	IMMUNLTR_MHCAT MHCAT
When did the medical history event start relative to the study reference period?	IMMUNLTR_MHSTRF MHSTRF
What was the relationship to the non-study medication?	IMMUNLTR_MHRELSNT MHRELSNT

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If contraindication was due to intolerance, which condition(s) indicated intolerance? *Check all that apply.*	☐ Serious Infection ☐ Hepatotoxicity ☐ Pancreatitis ☐ Leukopenia ☐ Thrombocytopenia ☐ Other **IMMUNLTR_INTCOND(n)_MHTERM** **If not "Other" then MHTERM**
If "Other", what was the other condition indicating intolerance?	**IMMUNLTR_INTCOND(n)_MHTERMOTH** **MHTERM**
What is the subcategory for the medication?	**ASA_CMSCAT** **CMSCAT;CMTRT**
Did the subject previously take any aminosalicylate (5-ASA) medications to treat Crohn's disease?	○ No ○ Yes **ASA_CMOCCUR** **CMOCCUR where CMTRT and CMSCAT="AMINOSALICYLATES"**
Did the subject discontinue any 5-ASA medications previously taken to treat Crohn's disease, prior to the baseline visit?	○ No ○ Yes **ASA_CMDISC** **[NOT SUBMITTED]**
Were any 5-ASA medications to treat Crohn's disease ongoing as of the baseline visit?	○ No ○ Yes **ASA_CMONGO** **[NOT SUBMITTED]**
What is the subcategory for the medication?	**CTCSTR_CMSCAT** **CMSCAT;CMTRT;FAOBJ**
What was the observation identifier?	**CTCSTR_CMLNKID** **CMLNKID; MHLNKID**
Did the subject previously take any corticosteroid medications to treat Crohn's disease?	○ No ○ Yes **CTCSTR_CMOCCUR** **CMOCCUR where CMTRT and CMSCAT="CORTICOSTEROIDS"**

cdisc				Site Number			Subject Number	

Prior Crohn's Disease Medications - High Level Only

Did the subject discontinue any corticosteroid medications previously taken to treat Crohn's disease, prior to the baseline visit?	○ No CTCSTR_CMDISC ○ Yes [NOT SUBMITTED]
Were any corticosteroid Crohn's disease medications ongoing as of the baseline visit?	○ No CTCSTR_CMONGO ○ Yes [NOT SUBMITTED]
Were contraindications to corticosteroids the reason for not using corticosteroids to treat Crohn's disease?	○ No CTCSTR_CMCREASOC ○ Yes NSCM.CMREASOC
If Yes, what were the contraindications to corticosteroid treatments? *Check all that apply.*	☐ Pre-existing medical condition CTCSTR(n)_CMCSCITYP ☐ Clinically significant adverse reaction to previous corticosteroid treatment [NOT SUBMITTED]
What is the identifier for the pre-existing medical condition?	CTCSTR(n)_CMMHNO Associate with related MH record via RELREC
What was the category of the medical history?	CTCSTR_MHCAT MHCAT
When did the medical history event start relative to the study reference period?	CTCSTR_MHSTRF MHSTRF
What was the relationship to the non-study medication?	CTCSTR_MHRELSNT MHRELSNT

cdisc	Site Number		Subject Number

Prior Crohn's Disease Medications - High Level Only

If contraindication was due to intolerance, which condition(s) indicated intolerance? *Check all that apply.*	☐ Osteonecrosis ☐ Osteoporosis ☐ Psychosis ☐ Uncontrolled diabetes ☐ Other **CTCSTR_INTCOND(n)_MHTERM** **If not "Other" then MHTERM**
If "Other", what was the other condition indicating intolerance?	**CTCSTR_INTCOND(n)_MHTERMOTH** **MHTERM**
Has the subject been unable to reduce (i.e., taper) the dose of corticosteroid at all without Crohn's disease symptoms recurring?	○ No ○ Yes **TPDEPIND_FAORRES** **FAORRES where FATESTCD = "TPDEPIND" and FAOBJ = "CORTICOSTEROIDS"**
Has the subject been unable to discontinue corticosteroid dosing completely without Crohn's disease symptoms recurring?	○ No ○ Yes **DCDEPIND_FAORRES** **FAORRES where FATESTCD = "DCDEPIND" and FAOBJ = "CORTICOSTEROIDS"**
Has the subject had a relapse (recurrence of Crohn's disease symptoms) within 3 months of discontinuation of corticosteroid medication?	○ No ○ Yes **RLDEPIND_FAORRES** **FAORRES where FATESTCD = "RLDEPIND" and FAOBJ = "CORTICOSTEROIDS"**

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