

# Monthly CSDR FAQ

**Q.** How do I Use the Monthly Comprehensive Safety Distribution Report?

**A.** The monthly comprehensive report (MCR) is a tool to be used by site staff to confirm receipt of safety information distributed by the DAIDS RSC Regulatory Information Center (RIC) for the studies conducted at their sites. Each month, the MCR contains information regarding safety distributions sent over the previous year beginning with the month identified on the report (i.e., if it is the January 2012 report the information listed will be those documents distributed from January 1, 2011 through January 31, 2012).

There are a number of ways you can view the information:

1. To view only those reports that pertain to a particular network or program (i.e.-ACTG, IMPAACT, HVTN, etc) filter the report by the GROUP (column F).

The filter function is automatically turned on when you open the document

Filter buttons are located on the top row, allowing you to sort the data

To sort by Group, click on the filter button in that box. A filter window will pop up below. Click on the "Select All" box, and this will uncheck the list of selections. Once they are blank, select the specific Groups you would like to sort by. Click OK and the results will filter.

Document/Number	Initial/Follow-up	Method of Distribution	DAIDS Distribution	Drug(s)	Group (ACTG, AIEDRP, HPTN, HVTN, INSIGHT)
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102456	Follow-Up			Zidovudine	
IND SR 2010-102554	Initial	Electronic	1/5/2011	Emtricitabine Tenofovir Disoproxil Fumarate Atazanavir Sulfate	
IND SR 2010-102554	Initial	Electronic	1/5/2011	Emtricitabine Tenofovir Disoproxil Fumarate Atazanavir Sulfate	
IND SR 2010-102554	Initial	Electronic	1/5/2011	Emtricitabine Tenofovir Disoproxil Fumarate Atazanavir Sulfate	
IND SR 2010-102554	Initial	Electronic	1/5/2011	Emtricitabine Tenofovir Disoproxil Fumarate Atazanavir Sulfate	

- To view the "Affected Protocol(s)" for the distributed safety information, filter the report by the Affected Protocol (column G).

Document/Number	Initial/Follow-up	Drug(s)	Group (ACTG, AIEDRP, HPTN, HVTN, INSIGHT)	Affected Protocol(s)
IND SR 2010-102456				
IND SR 2010-102456				
IND SR 2010-102456				
IND SR 2010-102456				
IND SR 2010-102456				
IND SR 2010-102456	Follow-Up	Efavirenz, Lamivudine, Zidovudine	ACTG	
IND SR 2010-102456	Follow-Up	Efavirenz, Lamivudine, Zidovudine	ACTG	
IND SR 2010-102456	Follow-Up	Efavirenz, Lamivudine, Zidovudine	CIPRA	
IND SR 2010-102456	Follow-Up	Efavirenz, Lamivudine, Zidovudine	HPTN	
IND SR 2010-102456	Follow-Up	Efavirenz, Lamivudine, Zidovudine	HPTN	
IND SR 2010-102456	Follow-Up	Efavirenz, Lamivudine, Zidovudine	IMPAA	
IND SR 2010-102554	Initial	Emtricitabine Tenofovir Disoproxil Fumarate, Atazanavir Sulfate	IMPAA	
IND SR 2010-102554	Initial	Emtricitabine Tenofovir Disoproxil Fumarate, Atazanavir Sulfate	IMPAA	
IND SR 2010-102554	Initial	Emtricitabine Tenofovir Disoproxil Fumarate, Atazanavir Sulfate	IMPAA	
IND SR 2010-102554	Initial	Emtricitabine Tenofovir Disoproxil Fumarate, Atazanavir Sulfate	ACTG	A5207

To sort by protocol, click on the filter button in that box. Follow the instructions above to select for the specific protocols you want to filter by.

Sort A to Z  
Sort Z to A  
Sort by Color  
Clear Filter From "Affected Protocol(s)"  
Filter by Color  
Text Filters

- (Select All)
- 1077BF
- 1077BF and 1077FF
- 1077FF
- 1077HS
- A5197
- A5207
- A5217
- A5225

OK Cancel

- To view a list of the Investigator Brochures or the Package Inserts that have been distributed since the DAIDS RSC contract award on April 15, 2010, go to the appropriate worksheet. For example, a list of IB documents distributed can be found on the worksheet "IB History" and a similar list for PIs can be found under the worksheet "PI History".

Investigator Brochure History (Drug)*	Version Date	Distribution Date
Atazanavir (Reyataz)	Feb-11	12-Jul-11 (P1020A)
Dapivirine (Vaginal Microbicide Gel)	Oct-08 Sep-10	10-Jan-11 (MTN-012 v1.0) 5-Jul-11 (MTN-012)
Dolutegravir (GSK1349572)	Jul-10 Feb-11	22-Dec-10 (P1093 v1.0) 29-Jun-11 (P1093)
Dolutegravir w/supplement (GSK1349572)	Jul-11	5-Aug-11 (P1093)
Etravirine (Intelence/TMC 125)	Oct-10	25-Oct-10 (A5241) 18-Nov-11 (P1090 v1.0)
Emtricitabine/Tenofovir Disoproxil Fumarate (Truvada)	Aug-10	16-Feb-11 (A5207, iPrEx, MTN-00)
ITX 5061	Mar-10	16-Jun-10 (A5277 v1.0)
LC002 DermaVir Patch	Jul-10 Jul-11	23-Jul-10 (P1049) 12-Jul-11 (P1049)
Lopinavir/Ritonavir (Kaletra)	May-10 May-11	10-Jun-10 (1077BF) 23-Sep-10 (1077FF v1.0) 22-Jul-11 (1077BF, 1077FF, P108)
Peginterferon alfa-2a (Pegasys) and Ribavirin (Copegus)	Jul-09 Jul-10 Jul-11	2-Apr-10 (A5269) 1-Dec-10 (A5269) 23-Sep-11 (A5269)
Raltegravir (Isentress)	May-10 Apr-11	17-May-10 (A5241, P1066) 16-May-11 (P1066) 18-May-11 (A5241)
Rifapentine	May-11	29-Aug-11 (A5279 v1.0)

Package Insert History (Drug)*	Version Date	Email Notification Date	
Abacavir Sulfate (Ziagen)	Sep-10	7-Jan-11	
	Nov-11	22-Dec-11	
Abacavir Sulfate and Lamivudine( Epzicom)	Sep-10	7-Jan-11	
	Feb-11	21-Apr-11	
Abacavir Sulfate/Lamivudine/Zidovudine ( Trizivir)	Sep-10	7-Jan-11	
	Mar-11	1-Jul-11	
Aldesleukin (Proleukin)	Apr-10	15-Jul-10	
	Aug-10	5-Oct-10	
	Mar-11	21-Apr-11	
	Aug-11	4-Oct-11	
Alendronate sodium (Fosamax)	Mar-10	11-Mar-10	
	Jan-11	21-Apr-11	
	Jul-11	4-Oct-11	
Atazanavir (Reyataz)	Apr-10	15-Jul-10	
	Feb-11	21-Apr-11	
	Oct-11	26-Oct-11	
Boceprevir (Victrelis)	May-11	13-Oct-11	(A5294 v1.0)
Buprenorphine/Naloxine (Suboxone)	Aug-10	21-Apr-11	
Coartem	May-09	7-Jan-11	
	Feb-10	4-Oct-11	
Contrimoxazole	Apr-03	7-Jan-11	
Darunavir (Prezista)	Apr-10	15-Jul-10	
		21-Apr-11	

For additional information on how to filter refer to the following website  
<http://office.microsoft.com/en-us/excel-help/about-filtering-HP005261132.aspx>