

Folic Acid for Vascular Outcome Reduction in Transplantation

ID NU	JMBER:	[FORM COI	DE: VDL	VERSI	ON: E	6/2	28/2004
LAST	NAME :							INITIALS	5:				
				1.	2.	3.	4.	5.	б.	7.	8.	9.	10.
Entry	Line	Co*	Seq*	Bottle Code	Expiration Date mm/yyyy	Total# Pills Dispensed	Date Distributed mm/dd/yyyy	Vitamin Start Date mm/dd/yyyy	Vitamin End Date mm/dd/yyyy	# Pills Returned	# Pills d Lost	Staff Code	Comments
	1			VDL1	VDL2	VDLC3	VDL3	VDL4	VDLE6	VDLE7	VDLE8	staff	VDL6A and VDL6B
	2												
	3												
	4					In ord	ler to cal	culate ad	herence,				
	5					use A	DHER d	ataset. 7	This				
	6					werge VDL,	es pill co and INF	unts from datasets.	FUP,				
	7												
	8												
	9												
	10												
	11												

* Contact Occasion (CO) represents the individual participant visits at which vitamins are distributed. Sequence Number (Seq), should be 00 if the distribution coincides with a scheduled study contact; otherwise it should be incremented.



Folic Acid for Vascular Outcome Reduction in Transplantation

ID NU	MBER:							FORM COD	DE: V	DL VEF	SION: D	12/02/03	
LAST NAME:													
	When there are problems with the vitamins or a patient has lost the vitamins and a new bottle must be distributed, this should be explained under comments. Extra lines are included for each patient to enter such additional distribution of vitamins. Note: Once a line has been entered into the DMS, record the date of entry below in the left hand margin of the paper form.												ce a
Entry	Line	Co*	Seq*	1. Bottle Code	2. Expiration Date (Month/Year)	3. Total # Pills Distributed	4. Date Distributed (Month/Day/Year)	5. Vitamin Start Dat (Month/Day/Y	1 te Year)	6. Staff Code		7. Comments	
	1			VDL1	VDL2	VDLC3	VDL3	VDL4	Blinc	l_staff_I	D VD	L6A and VDL6B	
	2												
	3				In orde	r to calcula	te adherer	nce,					
	4				use AD merges	HER datas	set. This s from FUP)					
	5				VDL, a	nd INF data	asets.						
	6												
	7												

*Contact Occasion (CO) represents the individual participant visits at which vitamins are distributed. Specifically for the VDL, 01 for the randomization visit, 03 for the twelve month visit, 05 for the twenty-four month visit, and 07 for the thirty-six month visit, and so on. If vitamins are distributed at a CO not scheduled in protocol for distribution, that CO should be used. Sequence Number (Seq), should be 00 if the distribution coincides with a scheduled study contact; otherwise it should be incremented.



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ID NU	MBER:							FORM CODE:	VDL VEH	RSION: C 11/05/03	
LAST NAME:											
	When there are problems with the vitamins or a patient has lost the vitamins and a new bottle must be distributed, this should be explained under comments. Extra lines are included for each patient to enter such additional distribution of vitamins. Note: Once a line has been entered into the DMS, record the date of entry below in the left hand margin of the paper form.										
Entry	Line	Co*	Seq*	1. Bottle Code	2. Expiration Date (Month/Year)	3. Total # Pills Distributed (100,200,400)	4. Date Distributed (Month/Day/Year)	5. Vitamin Start Date (Month/Day/Year)	6. Staff Code	7. Comments	
	1			VDL1	VDL2	VDLC3	VDL3	VDL4	Blind_staff_I	D VDL6A and VDL6B	
	2										
	3				In order	to calcula	te adherei	nce,			
	4				use AD merges	HER datas	set. This s from FUF	p,			
	5				VDĽ, ar	nd INF data	asets.	·			
	6										
	7										

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ID N	IUMBER:							FORM (CODE: VDL VERSION: B 08/27/02		
LAST	NAME :						INITIA	LS:			
	When there are problems with the vitamins or a patient has lost the vitamins and a new bottle must be distributed, this sexplained under comments. Extra lines are included for each patient to enter such additional distribution of vitamins. No line has been entered into the DMS, record the date of entry below in the left hand margin of the paper form.										
Entry	Line	Co*	Seq*	1. Bottle Code	2. Expiration Date (Month/Year)	3. Date Distributed (Month/Day/Year)	4. Vitamin Start Date (Month/Day/Year)	5. Staff Code	6. Comments		
	1			VDL1	VDL2	VDL3	VDL4 B	ind_staff	ff_ID VDL6A and VDL6B		
	2										
	3				In order	to calcula	te adheren	ce,			
	4				use ADI merges	HER datas pill counts	from FUP	,			
	5				VDL, an	d INF data	asets.				
	6										
	7										

*Contact Occasion (CO) represents the individual participant visits at which vitamins are distributed. Specifically for the VDL, 01 for the randomization visit, 03 for the twelve month visit, 05 for the twenty-four month visit, and 07 for the thirty-six month visit, and so on. If vitamins are distributed at a CO not scheduled in protocol for distribution, that CO should be used. Sequence Number (Seq), should be 00 if the distribution coincides with a scheduled study contact; otherwise it should be incremented.



Folic Acid for Vascular Outcome Reduction in Transplantation

ID N	IUMBER:							FORM (CODE:	VDL VERSIO	N: A 02/07/02
LASI	NAME:							INITIALS:		VDL vei	rsion A never used
	When t explai line h	here an ned und nas been	re prob der com n enter	lems with ments. Ex ed into t	the vita tra lines he DMS, 1	amins or a pa s are include record the da	tient has lost th d for each patien te of entry below	ne vitamins and a n at to enter such ac in the left hand	new bottl dditional margin o	e must be dist distribution of the paper fo	cributed, this should be of vitamins. Note: Once a orm.
Entry	Line	Co*	Seq*	1. Bottle Code	2. Lot #	3. Expiration Date (Month/Year)	4. Date Distributed (Month/Day/Year)	5. Vitamin Start Date (Month/Day/Year)	6. Staff Code		7. Comments
	1			VDL1		VDL2	VDL3	VDL4 Bli	nd_staff	_ID	VDL6A and VDL6B
	2										
	3	³ In order to calculate adherence,						herence,			
	4				use mer	ADHER ges pill (counts from	nis 1 FUP,			
	5				VDL	, and IN	IF datasets	-			
	6										
	7										

*Item 1 Contact Occasion (CO) represents the individual participant visits at which vitamins are distributed. Specifically for the VDL, 01 for the randomization visit, 03 for the twelve month visit, 05 for the twenty-four month visit, and 07 for the thirty-six month visit, and so on. If vitamins are distributed at a CO not scheduled in protocol for distribution, that CO should be used. Item 2, Sequence Number (Seq), should be 00 if the distribution coincides with a scheduled study contact; otherwise it should be incremented.