

Vitamin Distribution Log Instructions
VDL Version E: 06/28/2004
QxQ Date: 04/02/2005

I. GENERAL INSTRUCTIONS

The Vitamin Distribution Log (VDL) records distribution of study vitamins to participants.

At each scheduled distribution, participants receive a 4-bottle kit (100 pills per bottle) containing a one-year supply of tablets. Each participant is scheduled to receive vitamins at randomization (contact occasion 01), and contact occasions 03, 05, 07, and 09.

The vitamins are for participant use only. They should take one tablet daily, preferably at a regular time. Participants should continue taking other medications on their regular schedule.

For more information on vitamin distribution, read chapter 5: Vitamin Distribution in the FAVORIT Manual of Operations (MOP). Staff completing this form must be familiar with and understand chapter 14: Administrative Procedures in the Manual of Procedures. The form header information (ID, Last Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

Enter VDL data on the paper form **and** in the Data Management System (DMS). You may record many distributions on one paper form. If additional space is needed, please use a second paper VDL and staple them together.

For each distribution, record one answer per question.

‘Entry’ In this column, record the date each row of data was entered into the DMS. This date of entry is recorded only on the paper form.

‘Co’ Record contact occasion at which vitamins are distributed to participant. (For example, record 01 at randomization). If vitamins are distributed at a contact occasion not scheduled in the protocol for distribution, then that contact occasion should be recorded. If the vitamins are distributed between scheduled contact occasions, the last applicable contact occasion should be used and sequence number incremented. See Chapter 14 in the MOP for information on contact occasions.

‘Seq’ Record sequence number at which the vitamins are distributed. If the vitamins are distributed on a scheduled study contact occasion, then the sequence number will always be 00. If vitamins are distributed between scheduled contact occasions, then the sequence number should be incremented, starting at 01. See Chapter 14 for information on sequence numbers.

1. Record bottle code printed on the vitamin kit label (or bottle label). This code should match the bottle code assigned by the DMS at randomization on the Randomization Eligibility Form (REL). The assigned bottle code for each participant will remain unchanged throughout the study.

If participant needs vitamins and you do not have the needed bottle code in stock, then you will dispense letter-coded “back-up” vitamins. Contact the DCC to determine which letter-coded backup vitamins to use. In such cases, the letter code should be recorded here, along with a comment in Item 10 stating the reason the back-up vitamins were needed.

2. Record expiration date (month/year) printed on the vitamin kit (or bottle) label.
3. Record number of pills distributed. There are 100 pills per bottle.
4. Record date vitamins are distributed, using the U.S. order (month/day/year).
5. Record date (month/day/year) participant starts taking vitamins from this distribution.
6. Record date (month/day/year) that the participant stopped taking vitamins from this distribution. Typically this will be the day the participant returns the pill containers at their annual clinic visit. If the participants calls to inform you that they have lost all remaining vitamins from this distribution be sure the “end date” is the date they took the last pill. Proceed to item 7 and record the pill count for this distribution.
7. Record number of pills the participant returned to you from this distribution. Pill count should be based on the Vitamin End Date. If the participant forgets to bring the vitamins to the clinic visit you will need to call the participant and get the pill count over the telephone or have the participants mail the bottles to the clinic. If you are unable to obtain a pill count please set this item to permanently missing “= =” in the DMS, do not insert 0 for missing pill counts.
8. Record number of pills the participant lost from this distribution. Use an estimate if necessary. If no pills were lost, enter “0”. If you are unsure how many pills the participant lost please code this in the DMS as permanently missing “= =”, do not leave this item blank in the DMS.
9. Record initials of the staff member who distributed vitamins to the participant.
10. Leave blank, except to record reasons for non-standard vitamin distributions, such as replacement of lost/stolen vitamins, distribution due to missed/late appointment, etc. If you replace lost vitamins be sure to include in the comments which distribution is being replaced. For example, if the participant is distributed vitamins (bottle code 30) at the 01, 00 visit and they loose part of these and you have to send them a replacement then record on the new entry in the VDL with the following information:

Co= 01, Seq= 01, Bottle Code= 30, Expiration date=date on the bottle, Total pills dispensed =100, Date Distribute=Date you mailed the vitamins, Vitamin Start Date=Date participant calls to inform you they are starting the new pills, Vitamin End Date, #Pills returned and #Pills Lost=you will insert this information when the participant come in for their annual clinic visit, Staff Code=your initials, Comment="Mailed 1 bottle, 100 tablets to participant to replace 1 bottle of the 01, 00 distribution that was lost".

Vitamin Distribution Log Instructions
VDL Version D, 12/2/2003
QxQ Date: 12/4/2003

I. GENERAL INSTRUCTIONS

The Vitamin Distribution Log (VDL) records the distribution of study vitamins to participants. Each clinic assigns a “Clinic Vitamin Distributor” who is responsible for receiving, dispensing and maintaining inventory of the vitamins. It is important that the vitamins be stored in a secure, cool, dry place at room temperature and away from direct sunlight.

Participants receive either a high or low dose multivitamin. Each participant receives a kit, which will include a one-year supply of tablets in four bottles with 100 tablets per bottle. Each participant is scheduled to receive a kit at randomization (contact occasion 01), and contact occasions 03, 05, 07, and 09.

The vitamins are for the participant’s use only. They should take only one tablet per day, preferably at a regular time. Participants should continue taking any other medication on their regular schedule.

For more information on vitamin distribution, read chapter 5: Vitamin Distribution in the FAVORIT Manual of Operations (MOP).

Staff who complete this form must be familiar with and understand chapter 14: Administrative Procedures in the Manual of Procedures. The form header information (ID, Last Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

Enter VDL data on the paper form and in the Data Management System (DMS). You may record many distributions on one paper form. If additional space is needed, please use a second paper VDL and staple them together.

For each distribution, record one answer per question.

‘Entry’ In this column, record the date each row of data was entered into the DMS. This date of entry is recorded only on the paper form.

‘Co’ Record contact occasion at which vitamins are distributed to participant. (For example, record 01 at randomization). If vitamins are distributed at a contact occasion not scheduled in the protocol for distribution, then that contact occasion should be recorded. If the vitamins are distributed between scheduled contact occasions, the last applicable contact occasion should be used and sequence number incremented. See Chapter 14 in the MOP for information on contact occasions.

‘Seq’ Record the sequence number at which the vitamins are distributed. If the vitamins are distributed on a scheduled study contact occasion, then the sequence number will always be 00. If the vitamins are distributed between scheduled contact occasions, then the sequence number should start at 01. See Chapter 14 for information on sequence numbers.

1. Record bottle code, which was assigned at the randomization visit. This value can be found on the Randomization Eligibility Form. The bottle code on the vitamin kit/bottle label should match this bottle code. The bottle code will not change for the participant throughout the study.

If the participant needs a replacement kit/bottle and the clinic does not have the appropriate kit/bottle (code 01-32) available then the vitamins will be distributed from the back-up kits/bottles (misc. letter codes). The Clinic Vitamin Distributor will contact the DCC for which letter bottle code to dispense to the participant. This bottle code should be recorded here, along with a comment in Item 7 stating the reason the back-up kit/bottle was needed, and date distributed.

2. Record the expiration date (month/year) found on the vitamin kit/bottle label. Use leading zeros when necessary to fill in all fields. If the date is indicated with only two digits for month and two digits for year, enter a four digit year in the DMS (e.g., 03/04 is entered as 03/2004).
3. Record number of pills distributed. There are 100 pills per bottle.
4. Record date vitamins are distributed, using the U.S. order (month/day/year).
5. Record date (month/day/year) participant starts taking vitamins from this distribution.
6. Record the 3 initials of the staff member who distributed vitamins to the participant. If he/she only has two initials, then record and left justify the 1st name initial and the last name initial (in the DMS, the third space for this item will be blank).
7. Leave blank, except when there are non-standard vitamin distributions, such as replacement of lost/stolen vitamins, distribution due to missed/late appointment, etc. Record reason for distribution and number of bottles distributed. If pills were mailed back by participant, record number of bottles and pills received.

Vitamin Distribution Log Instructions
VDL Version C, 11/5/2003
QxQ Date: 11/5/2003

I. GENERAL INSTRUCTIONS

The Vitamin Distribution Log (VDL) records the distribution of study vitamins to participants. Each clinic assigns a “Clinic Vitamin Distributor” who is responsible for receiving, dispensing and maintaining inventory of the vitamins. It is important that the vitamins be stored in a secure, cool, dry place at room temperature and away from direct sunlight.

Participants receive either a high or low dose multivitamin. Each participant receives a kit, which will include a one-year supply of tablets in four bottles with 100 tablets per bottle. Each participant is scheduled to receive a kit at randomization (contact occasion 01), and contact occasions 03, 05, 07, and 09.

The vitamins are for the participant’s use only. They should take only one tablet per day, preferably at a regular time. Participants should continue taking any other medication on their regular schedule.

For more information on vitamin distribution, read chapter 5: Vitamin Distribution in the FAVORIT Manual of Operations (MOP).

Staff who complete this form must be familiar with and understand chapter 14: Administrative Procedures in the Manual of Procedures. The form header information (ID, Last Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

Enter VDL data on the paper form and in the Data Management System (DMS). You may record many distributions on one paper form. If additional space is needed, please use a second paper VDL and staple them together.

For each distribution, record one answer per question.

‘Entry’ In this column, record the date each row of data was entered into the DMS. This date of entry is recorded only on the paper form.

‘Co’ Record contact occasion at which vitamins are distributed to participant. (For example, record 01 at randomization). If vitamins are distributed at a contact occasion not scheduled in the protocol for distribution, then that contact occasion should be recorded. If the vitamins are distributed between scheduled contact occasions, the last applicable contact occasion should be used and sequence number incremented. See Chapter 14 in the MOP for information on contact occasions.

‘Seq’ Record the sequence number at which the vitamins are distributed. If the vitamins are distributed on a scheduled study contact occasion, then the sequence number will always be 00. If the vitamins are distributed between scheduled contact occasions, then the sequence number should start at 01. See Chapter 14 for information on sequence numbers.

1. Record bottle code, which was assigned at the randomization visit. This value can be found on the Randomization Eligibility Form. The bottle code on the vitamin kit/bottle label should match this bottle code. The bottle code will not change for the participant throughout the study.

If the participant needs a replacement kit/bottle and the clinic does not have the appropriate kit/bottle (code 01-32) available then the vitamins will be distributed from the back-up kits/bottles (misc. letter codes). The Clinic Vitamin Distributor will contact the DCC for which letter bottle code to dispense to the participant. This bottle code should be recorded here, along with a comment in Item 7 stating the reason the back-up kit/bottle was needed, and date distributed.

2. Record the expiration date (month/year) found on the vitamin kit/bottle label. Use leading zeros when necessary to fill in all fields. If the date is indicated with only two digits for month and two digits for year, enter a four digit year in the DMS (e.g., 03/04 is entered as 03/2004).
3. Record number of pills distributed. There are 100 pills per bottle.
4. Record date vitamins are distributed, using the U.S. order (month/day/year).
5. Record date (month/day/year) participant starts taking vitamins from this distribution.
6. Record the 3 initials of the staff member who distributed vitamins to the participant. If he/she only has two initials, then record and left justify the 1st name initial and the last name initial (in the DMS, the third space for this item will be blank).
7. Leave blank, except when there are non-standard vitamin distributions, such as replacement of lost/stolen vitamins, distribution due to missed/late appointment, etc. Record reason for distribution and number of bottles distributed. If pills were mailed back by participant, record number of bottles and pills received.

Vitamin Distribution Log Instructions
VDL Version B, 8/27/2002
QxQ Date: 8/27/2002

I. GENERAL INSTRUCTIONS

The Vitamin Distribution Log (VDL) records the distribution of study vitamins to participants. Each clinic assigns a “Clinic Vitamin Distributor” who is responsible for receiving, dispensing and maintaining inventory of the vitamins. It is important that the vitamins be stored in a secure, cool, dry place at room temperature and away from direct sunlight.

Participants receive either a high or low dose multivitamin. Each participant receives a kit, which will include a one-year supply of tablets in four bottles with 100 tablets per bottle. Each participant is scheduled to receive a kit at randomization (contact occasion 01), and contact occasions 03, 05, 07, and 09.

The vitamins are for the participant’s use only. They should take only one tablet per day, preferably at a regular time. Participants should continue taking any other medication on their regular schedule.

For more information on vitamin distribution, read chapter 5: Vitamin Distribution in the FAVORIT Manual of Operations (MOP).

Staff who complete this form must be familiar with and understand chapter 14: Administrative Procedures in the Manual of Procedures. The form header information (ID, Last Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

Data for the VDL must be entered on the paper form as well as in the Data Management System (DMS). The entire distribution history for a participant is captured on one paper form. If additional space is needed, please use a second paper VDL and staple them together.

For each item, record one answer per question.

‘Entry’ In this column, record the date each row of data was entered into the DMS. This date of entry is recorded only on the paper form.

‘Co’ Record the contact occasion at which vitamins are distributed to the participant. (For example, 01 must be recorded for the randomization visit.) If vitamins are distributed at a contact occasion not scheduled in the protocol for distribution, then that contact occasion should be recorded. If the vitamins are distributed between scheduled contact occasions, the last applicable contact occasion should be used and

sequence number incremented. See Chapter 14 in the MOP for information on contact occasions.

‘Seq’ Record the sequence number at which the vitamins are distributed. If the vitamins are distributed on a scheduled study contact occasion, then the sequence number will always be 00. If the vitamins are distributed between scheduled contact occasions, then the sequence number should start at 01. See Chapter 14 for information on sequence numbers.

1. Record the bottle code, which was assigned to the participant at the randomization visit. This value can be found on the Randomization Eligibility Form. The bottle code on the vitamin kit/bottle label should match this bottle code. The bottle code will not change for the participant throughout the study.

If the participant needs a replacement kit/bottle and the clinic does not have the appropriate kit/bottle (code 01-16) available then the vitamins will be distributed from the back-up kits/bottles (code A-H). The Clinic Vitamin Distributor will contact the DCC for which bottle code (A-H) to dispense to the participant. This bottle code should be recorded here, along with a comment in Item 7 stating the reason the back-up kit/bottle was needed, and date distributed.

2. Record the expiration date (month/year) found on the vitamin kit/bottle label. Use leading zeros when necessary to fill in all fields. If the date is indicated with only two digits for month and two digits for year, enter a four digit year in the DMS (e.g., 03/04 is entered as 03/2004).
3. Record the date vitamins are distributed to the participant, using the U.S. order (month/day/year).
4. Record the date (month/day/year) participant starts taking vitamins from this distribution.
5. Record the 3 initials of the staff member who distributed vitamins to the participant. If he/she only has two initials, then record and left justify the 1st name initial and the last name initial (in the DMS, the third space for this item will be blank).
6. Leave blank, except when there are non-standard vitamin distributions, such as replacement of lost/stolen vitamins, distribution due to missed/late appointment, etc., record reason for distribution and number of bottles distributed.