

INSTRUCTIONS FOR DRUG CARD ASSIGNMENT FORM 62

Form # 62A

This form is to be entered whenever masked drug cards (telmisartan/placebo) are assigned to a participant. Eight drug cards (40 mg pills) are to be dispensed to each participant at the baseline visit (B1 or SB1). Pill strength and quantity of drug cards assigned and dispensed at subsequent visits or dates of action will be determined on an as-needed basis.

The form may be generated at the time of the visit or date of action (whenever a change in medication occurs between study visits), or prior to the visit if necessary. For inventory and logistical reasons, the form should ideally be generated no more than one day before the visit. However, the form may be generated up to one week before the visit if necessary.

To generate the form, enter the pill strength and quantity of the drug cards being requested. The appropriate pill strength and quantity of drug cards will then be automatically assigned to the participant. Drug card numbers will appear on the generated form, which can then be printed and completed during the visit or date of action.

To complete the form, confirm the strength and quantity of pills remaining in the participant's possession and complete question #1. The strength and quantity of cards requested when the form was generated will appear in question #2. If the information is correct, check the "confirmed" box. If the information is incorrect, generate *another* form for any additional cards needed, or notify the DCC if any unnecessary cards were assigned. Drug cards assigned in error must *not* be dispensed and are to be returned to inventory only after the DCC has been notified and has corrected the database. Drug card labels, found on the drug cards, are to be affixed to the form in the designated areas, and participant ID code is to be written on the drug cards. Carefully compare all digits of the drug card numbers to those printed on the form whenever pulling drug cards for dispensation, affixing labels to the form, dispensing drug cards, and when entering data. Finally, the form completer and investigator are to sign and date the form.

Once completed, the form is to be entered within three business days after the visit or date of action.