I. Purpose

The E-TOMUS Incontinence Medication Audit Report will be used to document any changes, additions or discontinuations to medications a patient is taking for incontinence since the last study visit.

II. Administration

A. When and How to Use This Report/Form

The UITN Data Manager should print the E-TOMUS Incontinence Medication Audit Report prior to the visit, as the Interviewer will use it as the Form for updating incontinence medication information at each visit. This Report provides the Interviewer with a complete list of all incontinence medications and associated details per the patient's report at the last study visit. NOTE: The ET36 month report will pull all medications for UI from F363 at TF24. Any and all changes or discontinuations to medications a patient is/was taking for incontinence or newly prescribed medications for incontinence should be documented on the printed copy of the Report. This printed copy should be retained in the patient's binder as a Data Form.

The Incontinence Medication Audit is designed to be conducted via patient interview. Medical records can also be used to gather information about incontinence medications, as these two sources will match by the end of the visit.

All E-TOMUS visits are in-person by design. However, if patient will not or cannot come for an in-person visit and is willing to provide data via phone/mail, this interview can be completed via phone.

Materials needed:

- Printed Copy of E-TOMUS Incontinence Medication Audit Report
- Patient's Medical Record/Clinic Chart for reference

At the start of the Audit, the Interviewer should tell the patient that we are interested in all current incontinence medications including those that she has stopped taking since the last medication audit. The Interviewer should explain that we will record all prescribed incontinence medications, even if the patient has stopped taking them of her own accord. Per Interviewer discretion, some may find it easier to start out by asking the patient to report all prescriptions she is talking; then, as the Interviewer is trained to recognize incontinence medications, that subset of medications can then be identified and details of frequency and dates can be obtained and documented on those few.

Medications recorded on the Form must be written legibly and correctly. Check the spelling twice, as the spelling of generic drug names can be difficult. When in doubt, check for the correct spelling of the medication against the AHFS or other recognized drug reference texts.

B. Source

As these data are collected via patient interview, the Report/Form is the primary source document. There will be corroborating medical record documentation as well.

III. Section by Section Review

Section A: General Study Information

A1. **Study ID Number**: Study ID will be printed on this Report when it is printed from the DMS.

A2. **Visit Number**: Circle the appropriate visit code, i.e. ET36, ET48, ET60, ET72 or ET84.

VISIT	Frequency	Percent	Cum Freq	Cum Percent
ET36	368	30.62	368	30.62
ET48	350	29.12	718	59.73
ET60	309	25.71	1027	85.44
ET72	148	12.31	1175	97.75
ET84	27	2.25	1202	100.00

A3. **Date Form Completed**: Enter the date that the Audit is completed in the format of mm/dd/yyyy.

A4. **Interviewer's Initials**: Enter initials of certified TOMUS Interviewer completing the Audit. Enter first initial in first space provided, middle initial in second space provided and last initial in third space provided. If no middle initial, strike a mark in the second space. If last name is hyphenated or 2 last names, enter the initials of the first last name in the third space.

Section B. Incontinence Medication Audit

B1. **Since we last completed this medication audit, have you taken any incontinence medication prescribed by a medical doctor, nurse practitioner or physician's assistant? This includes any incontinence medications that you are currently taking, that you may have been taking prior to the last time that we completed this audit that you have continued to take, as well as incontinence medications prescribed by your doctor since that last audit that you are no longer taking now, or that you never filled at all?** Circle 1 (Yes) or 2 (No) accordingly; if "No," Form is complete.

MED_DIS_ADD	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	100	8.32	100	8.32
2: No	1102	91.68	1202	100.00

B2. **Are there any discontinuations or changes in dose frequency for incontinence medications since the last study visit?** Circle 1 (Yes) or 2 (No). If "Yes", document in table cells a-e accordingly; if "No", skip to B3.

DIS_INC	Frequency	Percent	Cum Freq	Cum Percent
.	1102	.	.	.
1: Yes	29	29.00	29	29.00
2: No	71	71.00	100	100.00

Frequency Missing = 1102

B2a. **Med ID Number:** The Med ID Number is a random number generated by the DMS and is preprinted on F373. This number is used for data entry purposes only. "Additions" do not require a Med ID number.

B2b. **Medication Name:** Incontinence medications that were being taken by the patient at the time of the last Audit are pre-printed on F373. Refer to these medications when confirming any changes in frequency or discontinuations of medications with the patient.

B2c. **Frequency:** Frequency codes (i.e. Regularly, PRN, Rx'd/Not Used) for incontinence medications that were being taken by the patient at the time of the last Audit are pre-printed on F373. Refer to this column when confirming any changes in frequency of incontinence medications with the patient.

B2d. **Start Date:** Start dates for medications that were being taken at the time of the last Audit are preprinted on the Report.

B2e. **Stop Date:** For all discontinued medications, ask the patient when she stopped taking the medication and record the date in mm/yyyy or mm/dd/yyyy format. For all changes in frequency of incontinence medications, ask the patient when she stopped taking the medication at the original frequency and record the date in mm/yyyy or mm/dd/yyyy format.

B3. **Are there any additional incontinence medications since the last visit?** Additions may include incontinence medications the patient started taking since the last audit, medications prescribed since the last audit even if they have since been stopped, and medications that were never filled. If there are any additions of incontinence medications since the last audit, circle 1 (Yes). If no additions since the last audit, circle 2 (No); form is complete.

ADD_INC	Frequency	Percent	Cum Freq	Cum Percent
.	1102	.	.	.
1: Yes	40	40.00	40	40.00
2: No	60	60.00	100	100.00

Frequency Missing = 1102

B3a. **Medication Name:** Probe thoroughly to get a complete list of current or recently prescribed incontinence medications. If the number of medications outnumbers the lines provided on the form, please continue the audit on the backside of the form, being sure to fill out the information for each column (a-d).

B3b. **Frequency:** For each additional incontinence medication recorded, ask the patient how often she uses the medication. Use the frequency codes as written below:

Code	**Description**
Circle code 1:	for medications taken regularly
Circle code 2:	for medications taken only as needed (prn)
Circle code 3:	for medications prescribed but not taken

B3c. **Start Date**: For all new incontinence medications, ask the patient when she began taking the medication. Record her response in mm/yyyy or mm/dd/yyyy format.

B3d. **Stop Date:** For all new incontinence medications that have since been stopped, ask the patient when she stopped taking the medication and record the date in mm/yyyy or mm/dd/yyyy format. If the patient reports that she is still taking the medication at this time, code 01/01/0101.