Importance of Patient Follow-up

Monica Yee, BA, CCRP
Program Manager, Prevention
SWOG Data Operations Center
Seattle, Washington
Follow-up begins...

- At the first contact with a potential study patient
  - Establish rapport and respect
  - Provide information so patient can make informed decision about participation
  - Clearly explain and **confirm the patient’s understanding of what is expected for follow-up** (big picture)
  - You assess the patient’s “fit” for the trial requirements
Why follow-up?

- Surveillance of the patient
- Monitor adherence
  - Identify and address issues early
- Retention to study
  - Ongoing effort and process of keeping patient interested, participating and committed to study
- Gather endpoint data to meet study objectives
You are key in facilitating study follow-up

Study Patient

Site Staff /Investigators

Statistics and Data Management Center
Be familiar with study endpoints, time points and trial objectives

• Know the study-specific primary outcome to understand the importance of the data to be collected and time points collected
• The “why,” “what” and the “when” for a study
Look for study endpoints and trial objectives in the protocol

- Section 1.0 – Objectives
- Section 10.0 – Criteria for Evaluation and Endpoint Definitions
- Section 11.0 – Statistical Considerations
Conduct follow-up at study-specific time points

• Section 9.0 – Study Calendar
  • Provides an **outline** of study parameters, tests, treatments, intervention, assessments, forms
  • For evaluation of eligibility and endpoints
  • **Cannot** rely only on the calendar

• Section 7.0 – Treatment/Intervention Plan
  • Provides **details and duration** for follow-up
  • Follow-up contact windows
  • Reasons for removal from intervention

• **Submit forms/data** per timelines in Section 14.0 – Data Submission
Example protocol objectives: S1105 Text Messaging Study

S1105 - Randomized Trial of Text-Messaging Intervention To Reduce Early Discontinuation of Adjuvant Aromatase Inhibitor Therapy in Women with Early Stage Breast Cancer

1.1 Primary objective

To determine the efficacy of a reminder message, sent by text message to mobile phones twice weekly, to improve adherence to adjuvant aromatase inhibitor (AI) therapy as determined by urinary AI levels in women with early stage hormone-sensitive breast cancer versus usual care.
Example: S1105 objectives

1.2 Secondary objectives

a. To compare the effect of a reminder message sent twice weekly to mobile phones as compared to usual care to improve adherence to adjuvant AI therapy according to self-report.

b. To explore the efficacy of the text message intervention for reducing early discontinuation as compared to usual care at 12, 24 and 36 months of adjuvant AI therapy in subgroups of breast cancer patients as defined by age group, stage, year of therapy, education, race/ethnicity, teaching hospital versus community hospital, AI-related side effects (as determined by serial questionnaires), insurance status, and prescription co-pay status.

c. To explore the reasons for early discontinuation of AI therapy in those who do discontinue in the intervention and control group by querying quality of life as assessed by the Functional Assessment of Cancer Therapy-Endocrine Subscales (FACT-ES) and symptoms and other issues related to hormonal therapy at each follow-up visit, using the Brief Pain Inventory (BPI-SF), and at annual visits the Beliefs about Medicine Questionnaire (BQM) and the Treatment Satisfaction Questionnaire for Medication (TSQM).

d. To conduct a sensitivity analysis assessing time to last evidence of adherence.
Example: S1105 at a glance

### 9.0 STUDY CALENDAR

**S1105**: "Randomized Trial of Text-Messaging Intervention To Reduce Early Discontinuation of Adjuvant Aromatase Inhibitor Therapy in Women with Early Stage Breast Cancer"

<table>
<thead>
<tr>
<th>REQUIRED STUDIES</th>
<th>Prestudy</th>
<th>Randomization</th>
<th>Baseline</th>
<th>Month 3*</th>
<th>Month 6*</th>
<th>Month 9*</th>
<th>Month 12*</th>
<th>Month 15*</th>
<th>Month 18*</th>
<th>Month 21*</th>
<th>Month 24*</th>
<th>Month 27*</th>
<th>Month 30*</th>
<th>Month 33*</th>
<th>Month 36*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History™</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitals Only: Height, Weight, Performance Status (PS)™</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Text Message Education Checklist ✔ ©</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 CareSpeak Subject Registration Form ✔ ©</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LABS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSH (if necessary)</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SPECIMENS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>INTERVENTION</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arm 1 Text messaging ✔</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arm 2 No text messaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>STAFF ADMINISTERED FORMS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 Prestudy</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 Cover Sheet for Patient Completed Questionnaires</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PATIENT AND STAFF-COMPLETED FORM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 Aromatase Inhibitor Usage Form</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PATIENT-COMPLETED QUESTIONNAIRES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 Cell Phone &amp; Text Messaging Use Questionnaire ✔</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 Baseline Demographics &amp; Medication Usage Questionnaire</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 FACT-ES (Version 4)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 BPI-SF</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1105 Patient Survey</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Example: S1105 Text Messaging

14.7  WITHIN 7 DAYS AFTER QUARTERLY VISITS (MONTHS 3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 33, AND 36):

Submit the following:

a.  Submit urine sample as described in Section 15.1. The SWOG Specimen Tracking System must be used for sample submission.

b.  S1105 Aromatase Inhibitor Usage Form (Form #13166)

c.  S1105 Cover Sheet for Patient-Completed Questionnaires (Form #16054)

d.  S1105 Cell Phone and Text Messaging Use Questionnaire (Form #61654) (For patients on text messaging arm only.)

e.  S1105 FACT-ES (Version 4.0) (Form #27668)

f.  S1105 Brief Pain Inventory – Short Form (Form #14375)

14.8  WITHIN 7 DAYS AFTER ANNUAL VISITS (MONTHS 12, 24, AND 36):

Submit the following:

a.  S1105 Patient Survey (Form #58996)

b.  S1105 Cover Sheet for Patient-Completed Questionnaires (Form #16054)
Do I continue to follow the patient?

• What if my patient...
  • ...is not eligible after randomization?
  • ...stopped taking the intervention early?
  • ...missed a study contact?
  • ...is too busy for active follow-up?
  • ...is ‘lost to follow-up’?
Follow every patient: Intent-to-Treat

- Analysis includes every subject in the treatment/intervention groups they were randomly assigned to.

- Regardless of:
  - Treatment/intervention received
  - Non-compliance
  - Protocol deviations
  - Withdrawal
Follow-up: Intent-to-Treat

• Ignores anything (the “noise”) that happens after randomization
• Reduces bias, maintains balance of randomization, preserves sample size
  • Avoids problems with justifying who is in or out of the analysis and what biases are produced
• In clinical practice, not all patients will be adherent to study requirements
  • “Once randomized, always analyzed”
• Key: Follow every patient with perseverance and patience
Follow-up Overview

- Once randomized, you are responsible for continued contact with the patient to provide quality data usable for statistical analysis
  - Data accurately reflect the study assessment requirements and patient’s responses to study questions
  - Follow-up assessments at specific time points for every study
  - SWOG Policy #30
- Forms designed for study endpoint collection
- Respond to queries for data clarification
- Some endpoints require confirmation
  - Specimen, image, source report submission
Strategies for follow-up

- Establish and practice interviewing strategies
  - Establish rapport – conversational, friendly
  - Keep contact focused – keep a fairly rapid flow to the contact
  - Listen attentively – listen for cues from the participant
  - Focus participant’s attention – stay in control of the contact
  - Be objective – keep your opinion to yourself; every participant is equally important
  - Clarify and probe for appropriate responses to study form questions – do not bias a participant’s response
  - Don’t record a “Don’t Know” answer too quickly – give the participant time to formulate an answer (pause vs. really don’t know)
  - Assure confidentiality – don’t reveal details of another participant’s interview outside the research team
  - Pay attention to details – know data submission requirements
Summary

• Follow-up of every study patient/participant is essential to the analysis of a trial
• Pave the way for smooth follow-up at your first contacts with a potential patient
• Know study endpoints and objectives and share this with the patient
• Conduct timely study contacts with the patient
• Collect and submit study data per protocol requirements

• Follow-up Breakout Discussion Sessions
  • 4:15 and 4:40 pm in the Toronto Room
  • Join the conversation and bring your insights and questions
  • We want to hear about your successes and challenges with patient follow-up