Creative Coordination: The Best Things in Life are Free

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Background

When resources are limited, clinical trial (CT) coordinators are often charged with performing Goliath tasks on a sling shot budget. Lower-budget clinical trials compete on the same field those sponsored by "Big Pharma" with their gigantic resources. Industry leaders often kick-start their studies with an Investigator Meeting to generate excitement, educate their team on study procedures, and form a community. To further entice engagement in their studies, they offer generous per-patient reimbursements and provide "extras" (e.g. study kits, advertising materials, central IRBs) that simplify study procedures and decrease the burden on site personnel. How do the kids from the sandlot compete with the New York Yankees?

The Long And The Short Of It

- **The Long Road:** Heavy demands on site time equates to less time for coordinators to spend extracting and reorganizing study procedure information from the protocol and manuals. The CT coordinators at Rho have developed extensive checklists for each study visit that outline how to prepare for the visit, conduct visit procedures, schedule the next visit, and complete data entry after the study visit. Each checklist is followed by required and optional source documents to capture most of the required data for each study visit, creating a visit packet - one link to all the Rho-provided documentation sites need. These visit packets take the burden of hours of preparation and review and condenses it into easy to follow directions.

VISIT #3: Week 3 Toxicity (+/- 3 days)

- Laboratory specimens must be obtained at approximately the same time of day at each visit.
- The site is responsible for any tubes required for the collection of local specimens and the applicable mechanistic specimens as noted below:
- Site coordinators will call subjects and/or their guardians weekly to remind the subjects to take their study therapy and notify them of any changes in study drug dose.
- Study drug will be dispensed during this visit, and study drug dosage may be changed based upon the results of the specimens collected during this visit.

PRE-VISIT PREPARATIONS

DAY BEFORE THE VISIT: Call subjects and remind him/her to bring their study drug and dosage labels to the visit.

Bring the following to the visit:

- A copy of the most recent version of the protocol.
- Questionnaires/Required Source Documents/Optional Source Documents included in this packet.
- Week 8 visit label bag for mechanistic specimens shipped and corresponding tubes. Required specimens:
  - Serum 2.0ml(MOD: 1: 3.0ml Gold top SST tube
- Local labs' required tubes: Please refer to the Local Labs Specimen Supply List for a list of suggested tubes.
  - Chemistries (serum calcium)
  - Urinalysis (calcium/creatinine ratio)

SITE-SPECIFIC STEPS/REMINDERS

- [ ]
- [ ]
- [ ]
- [ ]
- [ ]

CLINICAL ASSESSMENTS AND PROCEDURES:

- [ ] Concomitant Medications Assessment
  See protocol Section 8.8, Concurrent Medications and Therapy and Section 8.4, Prohibited Medications for further details.
- [ ] Adverse Events
- [ ] Collect study drug and conduct a pill count.
- [ ] Dispense study product (1 bottle of study therapy) and update the Subject Specific Drug Compliance Form.

LABS (SAMPLES ANALYZED LOCALLY):

- [ ] Chemistries: serum calcium
- [ ] Urine calcium/creatinine

MECHANISTIC STUDIES

REMINDERS

- Visit label bags include: required source document, 2 labels for each collection tube (1 for tube, 1 extra), 8 identical labels for each shipped tube (1 for the tube, 1 for the source document, 1 extra)
- Each tube will have a unique specimen number (within & under the bar code).
- See Lab Manual's Mechanistic Specimen Procedures & Supply List for processing & shipping instructions.

- [ ] 2.0(MOD: Draw 0.3ml blood into a 3.5ml Gold top SST tube
- [ ] *Same day as visit:* Create a shipment & obtain a tracking number using Preferred Shipping Carrier
- [ ] *Same day as visit:* EDC Entry: mechanistic specimen & LAB system Entry: shipment data.
  Note: EDC will send data to Lab system based on collected and required specimens. Coordinator will only need to provide shipment information based on these pre-generated entries in lab system. EDC entry must occur prior to lab system data entry.

Scheduling Week 6

Reminders:

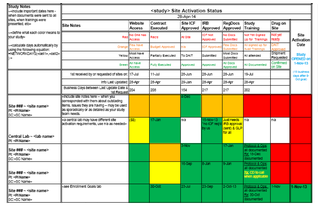
- The Week 6 visit should be scheduled within in a ±3 day visit window.
- Remind subjects to bring study drug and dosage labels back to the Week 6 visit.
- Review the subject's 2.0(MOD), serum calcium, and urine calcium/creatinine results with the site investigator. If these results mean any of criteria for change in study drug dose or study drug discontinuation (as outlined in Protocol Sections 8.5.2, *Management of Known Toxicities to Study Product*, or 8.11.1, *Study Treatment Discontinuation*) notify the subject of the required dosage change immediately.
- Work with the site investigator to complete a prescription request form for the site pharmacist prior to the Week 6 visit.

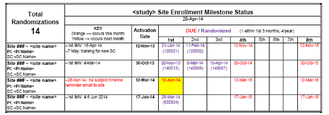
Data Entry

- [ ] Within 1 day of notifying Rho via phone/email (within 24 hours of awareness), enter SAE data into the EDC system
- [ ] Within 2 weeks of the Week 3 visit, enter all available subject data into the EDC system.
- [ ] If the subject's study drug dose changes in between study visits, update the Initial/Change in Study Drug Dose eCRF in the "Ongoing Logs" folder within the EDC system.

This visit checklist was created in Microsoft® Word

- **Short and Sweet**: Demands on site personnel time have never been higher and in the fast paced world of clinical trials, information needs to be available at a glance. CT coordinators have provided short, digestible, pulses of integral study information to sites in a variety of ways from activation or enrollment heat maps which inform protocol teams when their sites' performance is in the red to tweets in study newsletters.

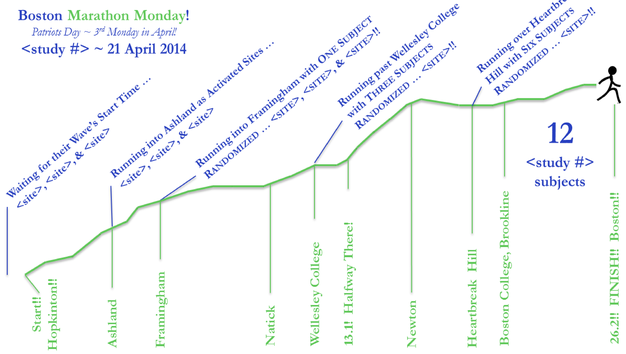




- *RhoRAND™ sends randomization notifications only on Day 0 telling your pharmacist what to dispense at each study visit. #dispensewhat #dispensewhen #print&save*
- *Remember- subject visits should not be scheduled on Fridays as the mechanistic lab is closed on the weekends. #PBMCs&Plasma #TGIF #nooneshere*
- *The Pharmacy Manual was updated on March 10th. #drugstorage #alerttemperatures #pillcountsafety*

Let Your Personality Shine

If your team call occurs on a holiday (even a regional one), consider personalizing your regular study update. It will be fun for you & interesting for your team!



**Disclaimer: As your Rho Coordinator was born & bred in Massachusetts before being adopted by the Tar Heel State … you may experience a few geographical references along the way!*

This update was created in Microsoft® PowerPoint using a course map as a guide.

Reframe Friendly Competition

As clinicians, our investigators want to improve the lives of their patients.

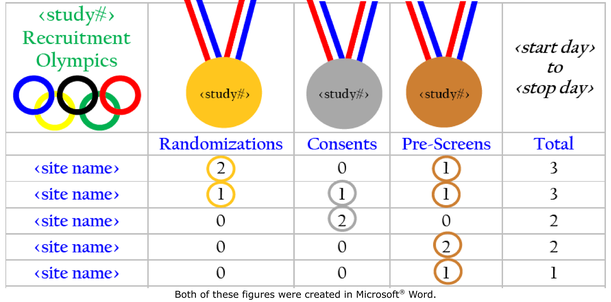
As investigators, they want to increase the breadth & depth of medical knowledge.

As doctors, they want to be their best.

As driven people, they want to be THE best.

Why not flavor that innate competition with current events?

Advance to the final four by scoring randomizations and setting screens! It's anyone's game!



	Randomizations	Consents	Pre-Screens	Total
<site name>	2	0	1	3
<site name>	1	1	1	3
<site name>	0	2	0	2
<site name>	0	0	2	2
<site name>	0	0	1	1

Both of these figures were created in Microsoft® Word.

Brand Your Study

Our study's official documentation needs to be professional. However, there are many other communications that can stand out from the crowd.

- Create a logo or mascot! If your study doesn't have an official logo, peruse Microsoft's® clipart & pick one for your study. This little bookworm appears on all newsletters for a trial investigating whipworm ova.
- AVOID DEFAULT FONTS! We all read hundreds of documents a day in Times New Roman or Calibri. Choose another easily legible font for all your *Emails*, Newsletters, Training Presentations, and Informal Tools.
- Colorful source documents! If your study has to provide hard copies of specific source documents (i.e. ones requiring scales of a validated length), print them on colored pieces of paper. Not only will these documents stand out in a sea of paper, but they also help your monitor quickly identify important items.
- Eye-catching headlines! When creating and sending informative updates, capture your sites' attention by peppering your subject lines and titles with pithy catchphrases. "Dum…da…dum.dum…Data queries are coming!" "Winter weather strikes again - shipments delayed!" "To Be or Not To Be … Eligible?"

Would Information By Any Other Name Smell As Sweet?

I before e except after…….

For years rhyming and mnemonics have been utilized to help us remember rules to live by. Medical professionals are inundated with dry, dense, monotonous communications. Keep your study vibrant with the most abundant resource at your disposal, your words.

An Ode to Reinforcing Study Entry Criteria … in the key of your favorite TV theme song

The subjects…. can't be on vitamin D greater than 800 IU
And if they've had rituximab lately then that excludes them too
We won't list all of the criteria here because that would be a bore
But please check out this protocol, the criteria are in Section 4

The study …lasts 18 weeks, with minimal expectations of harm
And the subjects with receive Vitamin D 400 or 6000IU depending on the arm
At Baseline and Week 18 we will conduct an OGTT
And will have visits to carefully check for toxicity

Channeling E.E. Cummings to Encourage Enrollment

The time for our study has come, this is our time to enroll
I know it takes hard work, on top of busy schedules, it takes its toll
But we have 52 subjects, who said they would give this protocol a shot
Let's find these last 28 subjects, let's give it all that we've got

Getting Personal

When working with multiple sites to complete a clinical trial, a sense of community, understanding, and team goals is imperative. However, the distance between sites (and lack of face-to-face time) can lead to a sense of dissociation and lack of engagement among your team members. To offset that impediment:

- Encourage sponsor and protocol chair recognition of site achievements
- Highlight exemplary performance in each study communication
- Include pictures of your team performing study tasks in your newsletters
- Introduce one team member in each newsletter by describing "5 things you didn't know about …"

Summary

Even when you don't have a large budget at your disposal, you still have a plethora of tools at your fingertips. You may need to be a bit more creative in implementing them but that makes them all the more memorable.

Rho®
Giving flight to research

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