MULTITASKING AND MANAGING A COORDINATOR'S VARIED ROLE

PRESENTATION OBJECTIVES

- Provide Overview of Research Coordinator responsibilities
- Discuss tips and tools for organizing, planning, and prioritizing coordinator tasks/responsibilities
- Provide tips/tools and mind-set needed to tackle different phases of clinical trial
- Other tips and organization considerations for coordinators

RESEARCH COORDINATORS MANY RESPONSIBILITIES

HOW DO YOU GET ALL OF THESE RESPONSIBILITIES AND TASKS COMPLETED?

This Photo by Unknown Author is licensed under CC BY-SA-NC

WHERE DO YOU START – WHEN THERE IS SO MUCH TO DO?

- Need to have a clear understanding of all your job responsibilities.
  - Should be clear when hired – did you get a job description?
    - What if job description lists 'Other duties as assigned'?
  - How many studies are you responsible for? (type of study-PI initiated vs. Sponsor)
- Know what tasks are associated with your job responsibilities (daily/monthly/yearly)
  - How familiar/confident are you with the responsibilities?
  - New coordinators - you should have lots of questions about what needs to be done.
- Identify the other staff/investigators/sponsors/stakeholders who you rely on or rely on you?
  - Do you understand their roles and responsibilities and how they interact with your tasks?

IDENTIFY THE TASKS/RESPONSIBILITIES

- Routine Existing Study/Project Tasks
  - Routine IRB submissions (annual review)
  - Regulatory Documentation
  - Participant/sponsor visits
  - Data monitoring
  - Team/Staff meetings
- Future Planned/Coordinated Tasks
  - Special projects
  - New Study Start-Up
- Unexpected Tasks
  - SAEs, UPs
  - Study visits - problems with equipment, unexpected staff time off, participant no-shows, etc
  - Weather, database/computer problems, etc
  - Others?

DEVELOP ORGANIZED TASK LISTS

Items to consider when developing/organizing a 'Task/to-do List'

- Type of list you will use: hand written, electronic list, a task App
- Compile a complete list of *routine* and *future* planned tasks. Determine how much of your week is spent on routine tasks.
- Consider breaking down big projects into separate smaller tasks
- Consider grouping tasks by those that are similar or within a family of task organized by family of group of tasks
- Consider assigning each tasks a level of importance high/medium/low to help with prioritization

DEVELOP ORGANIZED TASK LISTS

- For non-routine tasks – assign/establish a realistic due date
- Are you collaborating with others on tasks? Are those tasks clearly defined with due dates?
- Prioritize your tasks – based on importance and due date
- A Task List will consistently change. Devote some time each week to looking over and re-evaluating your list.

PRIORITIZING TASKS

Modified - Eisenhower Priority Matrix - Prioritize tasks based on importance and urgency

Key to prioritizing – determining what are truly High Importance/Urgent (HI/U) tasks. How much of your week is spent working on HI/U items? Not everything can be of HI/U

	Urgent	Not Urgent
High Importance	DO FIRST Ex.	SCHEDULE TIME TO COMPLETE Ex.
Medium/Low Importance	CONSIDER DELEGATING TO OTHER STAFF Ex.	Don't Act Keep on Radar until Urgent

PRIORITIZING TIPS

- Plan that you will have to address unexpected/urgent tasks
- Plan/schedule uninterrupted time during your week to work on priority tasks (close office door, turn off email; block time in calendar, etc.)
- Develop a routine for the daily routine HI/U tasks (ex. First thing in morning).
- Don't allow the *High Important/Not Urgent* tasks to become "urgent" - stick to time scheduled to complete
- When the HI/U tasks become unmanageable, unstainable, overwhelming - discuss with supervisor.

STAYING ORGANIZED DURING DIFFERENT PHASES OF A RESEARCH STUDY

HOW DO YOU GET IT ALL DONE?

s Photo by Unknown Author is licensed under CC BY-SA-NC

BREAK THE WHOLE DOWN INTO SMALLER PARTS
CLINICAL RESEARCH TRIAL LIFECYCLE

What tasks are associated with each smaller part?

START-UP

Start-up documents

- 1572
- CVs, medical licenses, financial disclosures, required education/trainings
- Other documents required by sponsor as needed

IRB Submission

- Protocol, Investigational Brochure, Consents, Volunteer-facing documents
- Are you using a Central IRB or a Local IRB, and what are their requirements
- What is your IRB Deadline?

Planning

- Plan Site Initiation Visit Date
- Plan study visits with collaborators (Investigational Pharmacy, Clinical Research Space, Clinicians)
- Plan resources
- Identify required resources (Investigational Pharmacy, Research Facility, Nursing, Phlebotomists, Clinicians)

ACTIVATION/RECRUITMENT

Activation Documents
- Site Activation Letter
- IRB Approval
- IRB approved consent/e-consent, finalized source documents

Recruitment
- Staffing to recruit
- Posters, advertising medium, advertising budget
- Clinicians, coordinator, nursing staff availability for consents, screening visits

Reporting
- Evaluate recruitment progress
- Reporting – accrual vs screen fail reason

STUDY EXECUTION

Preparation
- All source documents in order
- Lab requisitions and labels prepared for study
- Volunteers invited, and initial visits scheduled

Visit Schedule
- Calendar planned and confirmed with collaborators
- Volunteers provided with/can commit to scheduled study visits
- Clinicians are scheduled

Admin/ Regulatory
- Data entry
- Monitoring visits
- Adverse Event/Serious Adverse reporting
- Troubleshooting

CLOSEOUT

SPONSOR
- Monitor close-out
- Clean up – outstanding queries
- IRB closeout acknowledgement to sponsor

IRB
- Submit close-out notification to your IRB
- Maintain IRB close-out acknowledgement

ARCHIVE
- Archive volunteer and regulatory binders – electronic or paper?
- If using EHR such as EPIC, Ensure all volunteers removed from study.

USE TIME YOUR TIME / BUILD IN EFFICIENCES

- **While waiting for sponsor approval of documents prior to IRB submission**
  - Plan/Develop visit calendar: Investigational Pharmacy, Clinician Schedules, CRC
  - Develop Source Documents if required
  - Follow-up with study team members re: outstanding trainings
  - Create a training grid to verify all training requirements/CVs are completed
- **While waiting for IRB approval**
  - Plan – SIV date, invites – any other required start-up meetings
  - Inventory Supplies for study
  - Finalize your source documents
  - Review your study start-up checklist, finalize visit day checklists
- **During Recruitment (if scheduling cohorts in groups)**
  - Continue with on-study source documents
  - Use a shared calendar
- **On-Study Phase**
  - schedule volunteer visits on same day or as closely as possible
  - Block admin time on your calendar for regulatory tasks

DEADLINES AND COMMUNICATION

- Know your deadlines and prioritize using deadlines as your guide
  - IRB Deadlines
  - Sponsor Timeline
  - Planned Study Start Date
- Set Timelines
  - Gantt Charts
  - Study Planning Tools/Calendars
- Communicate/Set expectations
  - How long does it take to activate a study at your site?
  - Estimate reasonable recruitment goals based on past studies

VISIT PLANNER TOOL

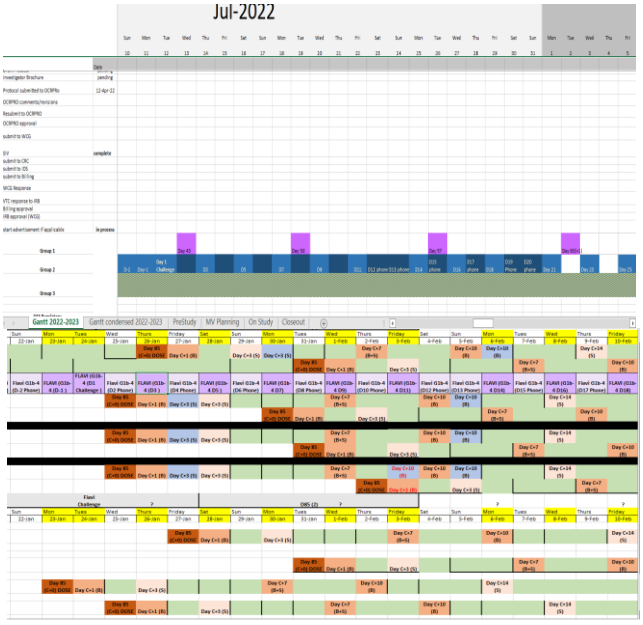
- Simple Excel Spreadsheet with auto-fill follow-up dates to assist in visit planning

	Visit Window	Study: #
N=? Cohort___ Group		
screening window opens		Friday, May 7, 2021
0 Dose		Tuesday, July 6, 2021
4(-1)	± 1	Friday, July 9, 2021
6(+1)	± 1	Tuesday, July 13, 2021
8	± 1	Wednesday, July 14, 2021
10	± 1	Friday, July 16, 2021
12	± 1	Monday, July 19, 2021
14	± 1	Tuesday, July 20, 2021
16	± 1	Friday, July 23, 2021
21	± 1	Tuesday, July 27, 2021
28	± 2	Tuesday, August 3, 2021
56 (unblinding)	± 14	Tuesday, August 31, 2021
90(+1)	± 10	Tuesday, October 5, 2021
150	(+14)	Friday, December 3, 2021
180(-4)	(+28/-14)	Wednesday, December 29, 2021
180+28 day window		
180+28		Sunday, January 30, 2022

Enter first visit date here Autofill follow-up visits

GANTT IT OUT

- Study Start-up Phase
- Plan your timeline
- Compare to other tasks/studies going on
- Provides overview/forecast of what's coming



Learning: Project Management Simplified – Linkedin – Chris Croft

CHECKLISTS

- VISIT DAY CHECKLISTS – ASSIST IN COMPLETING VISIT DAY ACTIVITIES
- CHECKLIST NOTEBOOK OF ONGOING ACTIVITIES
- ELECTRONIC CHECKLISTS IF YOU PREFER

WORKING FILES

- In process activities
- Easy to refer back to after attention pulled to another task
- Transition to appropriate binder when task is complete

This Photo by Unknown Author is licensed under CC BY-NC

STUDY EXECUTION PHASE - MINDSET

This Photo by Unknown Author is licensed under CC BY-SA

- **Just Do it Now – day-to-day activities!**
- Plan for "just do it now" activities. If can't do it right now, add it to a checklist.
  - Data entry: complete it on the same day as the visit.
  - PI/colleague calls/emails you with an "ask", just do it now if you can. If you can't do it now, provide estimated timeline for completion.
  - Monitor visits – complete as much follow-up as possible during the visit – less to do later
  - Look for efficiencies

OTHER TIPS AND ORGANIZATIONAL CONSIDERATIONS

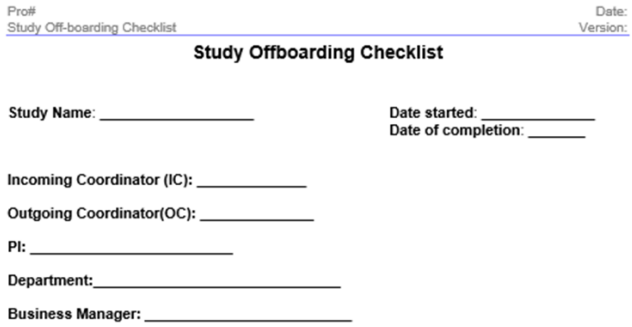
TAKING ON A NEW STUDY

Study Implementation Checklist

- Study registration (Institutional tracking)
- Budget development
- Regulatory
  - IRB/IBC/other institutional reviews
  - Files
- Personnel access
  - Study supply storage, EDC, IWRS, etc.
- Study medication
- Ancillary services
  - Participant payment, EMR, etc.
- Study supplies and storage
- Site specific processes (SOP)

TAKING OVER AN EXISTING STUDY

- Consider using a **study handoff/offboarding checklist**
  - Study specific access needs
  - Study status
  - Regulatory status/files
  - Site specific processes/procedures
  - Study medication
  - Supplies and equipment
  - Study participant status



Pro#
Study Off-boarding Checklist
Date:
Version:

Study Offboarding Checklist

Study Name: _____

Date started: _____
Date of completion: _____

Incoming Coordinator (IC): _____

Outgoing Coordinator(OC): _____

PI: _____

Department:_____

Business Manager: _____

SCHEDULING

SIV/IMV/Close out

- Determine if any group has limiting factors (pharmacy, PI, etc) and start with that group

Standing study team meetings

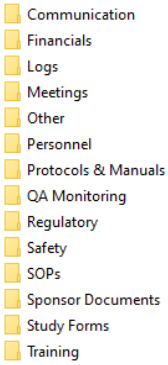
- Check in as a team periodically
- Standing meeting with PI (document signatures)
- Set agenda

Participant Scheduling

- Utilize a shared calendar

FILE ORGANIZATION

Use templates for electronic study file storage
- Allows for any member of the study team to step in and know where to locate documents



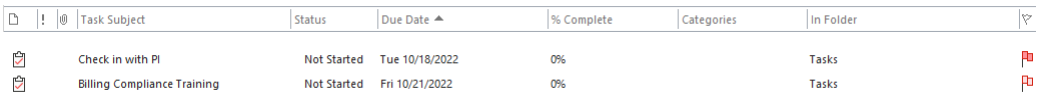
Document sharing
- Box, Microsoft Teams, OneDrive, etc
- Be aware of privacy issues (follow institutional guidelines for file sharing, especially with PHI)

BOX

Microsoft Teams

EMAIL AND WEB BROWSER ORGANIZATION

Email
- Make a subfolder for each study in your inbox
  - Also assists with archiving relevant communications
- Utilize tasks lists/flag emails
- Shared calendar



Task Subject	Status	Due Date	% Complete	Categories	In Folder
Check in with PI	Not Started	Tue 10/18/2022	0%		Tasks
Billing Compliance Training	Not Started	Fri 10/21/2022	0%		Tasks

Bookmark commonly used webpages
Save your passwords!

ORAGNIZATION OF STUDY OFFICE/DESK

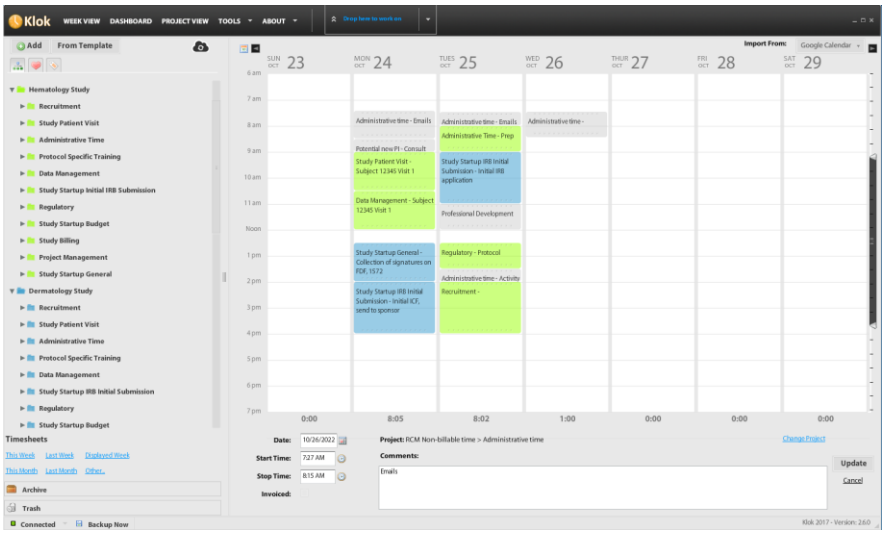
Organization doesn't stop at prioritizing your 'task list':

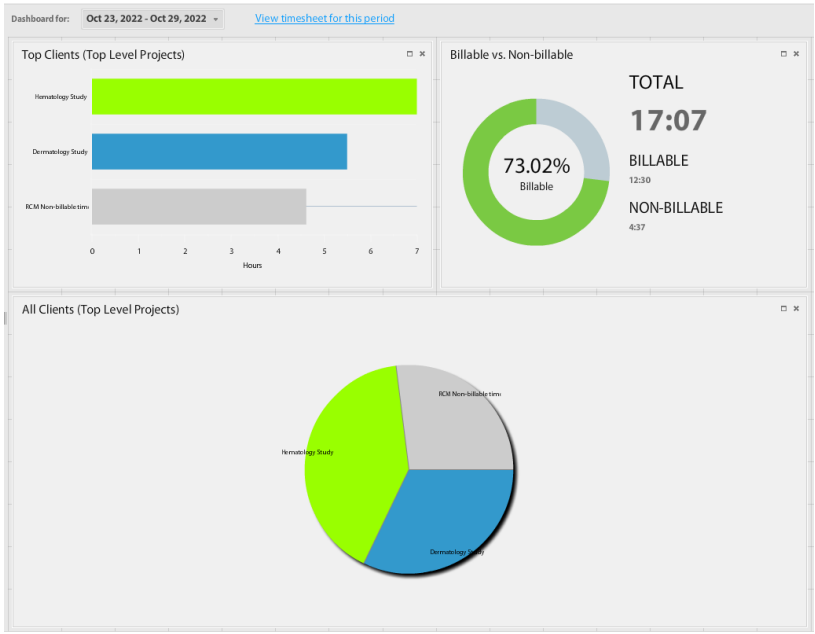
- What sort of study supply area did you inherit?
  - Remove/destroy old/expired study items (help avoid mistaken use)
  - Organize study supplies (label with study identifier and group materials for one study together)
  - Organize study equipment/tools/binders (name of study, contact name and phone/email)
- Shared office mentality
  - Dedicate a few hours monthly/quarterly for all staff to organize.
- Organize/de-clutter your personal work space
  - Archive old study binders and items no longer used
  - Dedicate some desk space to keep free from folders/papers so you can work (not lose items)

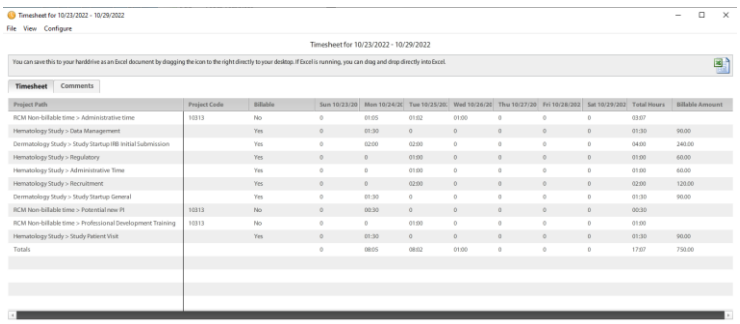
TIME MANAGEMENT

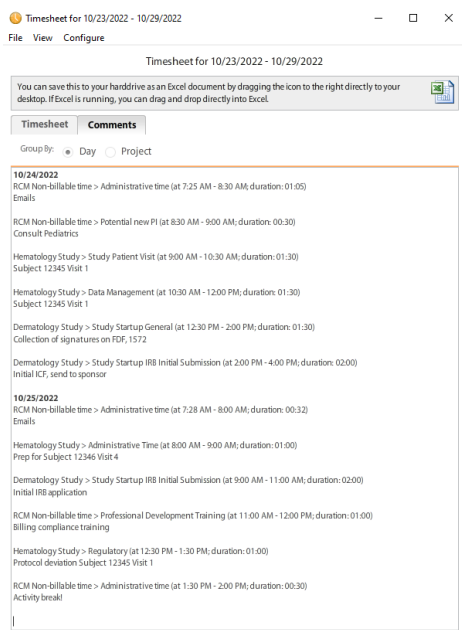
Tips to effectively use your time:

- Be intentional about how you spend your time
- Create a time audit




Dashboard for:
Oct 23, 2022 - Oct 29, 2022
View timesheet for this period
Top Clients (Top Level Projects)
Hematology Study
Dermatology Study
RCM Non-billable time
0
1
2
3
4
5
6
7
Hours
Billable vs. Non-billable
73.02%
Billable
TOTAL
17:07
BILLABLE
12:30
NON-BILLABLE
4:37
All Clients (Top Level Projects)
RCM Non-billable time
Hematology Study
Dermatology Study


Timesheet for 10/23/2022 - 10/29/2022
File View Configure
Timesheet for 10/23/2022 - 10/29/2022
You can save this to your harddrive as an Excel document by dragging the icon to the right directly to your desktop. If Excel is running, you can drag and drop directly into Excel.
Timesheet
Comments
Project Path
Project Code
Billable
Total Hours
Billable Amount
RCM Non-billable time > Administrative time
Hematology Study > Data Management
Dermatology Study > Study Startup IRB Initial Submission
Hematology Study > Regulatory
Hematology Study > Administrative Time
Hematology Study > Recruitment
Dermatology Study > Study Startup General
RCM Non-billable time > Potential new PI
RCM Non-billable time > Professional Development Training
Hematology Study > Study Patient Visit
Totals


Timesheet for 10/23/2022 - 10/29/2022
File View Configure
Timesheet for 10/23/2022 - 10/29/2022
You can save this to your harddrive as an Excel document by dragging the icon to the right directly to your desktop. If Excel is running, you can drag and drop directly into Excel.
Timesheet
Comments
Group By: Day Project
10/24/2022
RCM Non-billable time > Administrative time (at 7:25 AM - 8:30 AM; duration: 01:05)
Emails
RCM Non-billable time > Potential new PI (at 8:30 AM - 9:00 AM; duration: 00:30)
Consult Pediatrics
Hematology Study > Study Patient Visit (at 9:00 AM - 10:30 AM; duration: 01:30)
Subject 12345 Visit 1
Hematology Study > Data Management (at 10:30 AM - 12:00 PM; duration: 01:30)
Subject 12345 Visit 1
Dermatology Study > Study Startup General (at 12:30 PM - 2:00 PM; duration: 01:30)
Collection of signatures on FDF, 1572
Dermatology Study > Study Startup IRB Initial Submission (at 2:00 PM - 4:00 PM; duration: 02:00)
Initial ICF, send to sponsor
10/25/2022
RCM Non-billable time > Administrative time (at 7:28 AM - 8:00 AM; duration: 00:32)
Emails
Hematology Study > Administrative Time (at 8:00 AM - 9:00 AM; duration: 01:00)
Prep for Subject 12346 Visit 4
Dermatology Study > Study Startup IRB Initial Submission (at 9:00 AM - 11:00 AM; duration: 02:00)
Initial IRB application
RCM Non-billable time > Professional Development Training (at 11:00 AM - 12:00 PM; duration: 01:00)
Billing compliance training
Hematology Study > Regulatory (at 12:30 PM - 1:30 PM; duration: 01:00)
Protocol deviation Subject 12345 Visit 1
RCM Non-billable time > Administrative time (at 1:30 PM - 2:00 PM; duration: 00:30)
Activity break!

SELF CARE

Take time to prioritize yourself!

- Take an activity break
- Drink water
- Pack a healthy lunch

- Read or listen to a podcast
- Organize your workspace
- Write daily to-do list

- Make time to meet a new person
- Attend workplace social events
- Do something nice for a coworker

•Practice deep breathing
•Keep a gratitude journal
•Ask for help

It is not possible to do all the things all the time!!!

BREAKOUT ROOMS

- Your chance to share your experiences!
- Approximately 10 people in each room with facilitator
- Don't be shy!
- After breakout rooms, will reconvene to discuss

FOR DISCUSSION:

You are the coordinator experiencing unexpected events in your workday.

Based on the information discussed in today's presentation or from your own experience, what are some of the tools, strategies or ways you might manage or think through the following scenario?

- 5 participants are scheduled for a planned study visit today. Usually your co-worker coordinates the visit but you just discovered they are going to be out sick for next 5 days. You are the back-up coordinator for this study.
- There is a data entry deadline (includes the 5 participants being seen today).
- Continuing review for one of your other studies is due Friday.
- The IRB deadline for an upcoming study is due next Wednesday. You still need to complete the regulatory paperwork and consent draft. The Sponsor and PI would like to begin study enrollment within the next 8 weeks.
- You are preparing for a monitoring visit scheduled next Tuesday.
- You receive an email from your PI containing a special reporting request for their research publication.
- A new nurse requires Site Initiation/Protocol training and needs to be added to the Delegation of Authority Log before they can work with study participants for your study. The nurse manager requests this be completed today due to staffing challenges.

HOW MIGHT YOU PRIORITIZE?

- Using the Eisenhower Priority Matrix – How might you prioritize tasks based on importance and urgency ?
- What communication would you consider having?
- Are there other tools or strategies you would like to discuss?

	Urgent	Not Urgent
High Importance	DO FIRST Ex.	SCHEDULE TIME TO COMPLETE Ex.
Medium/Low Importance	CONSIDER DELEGATING TO OTHER STAFF Ex.	Don't Act Keep on Radar until Urgent