



# Setting Up Your IIS Program for Success – From Ideation to Dissemination

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# Agenda

- 01 Investigator-Initiated Study (IIS) Basics
- 02 Starting from the ground up
- 03 Who are the key players and committees?
- 04 What are the key performance indicators?
- 05 What does success look like?
- 06 Takeaways



# Investigator-Initiated Study (IIS) Basics

## IISes are...

- Clinical studies **initiated and managed by a nonpharmaceutical company researcher(s)**
  - Individual investigator
  - An institution
  - Group of institutions
  - Collaborative study group or a cooperative group
- **IISes go by many names**, including:
  - Investigator-Initiated Trials (IITs)
  - Investigator-Sponsored Trials
  - Noncommercial Trials
  - Academic Clinical Trials
  - Physician-Led Studies, etc.

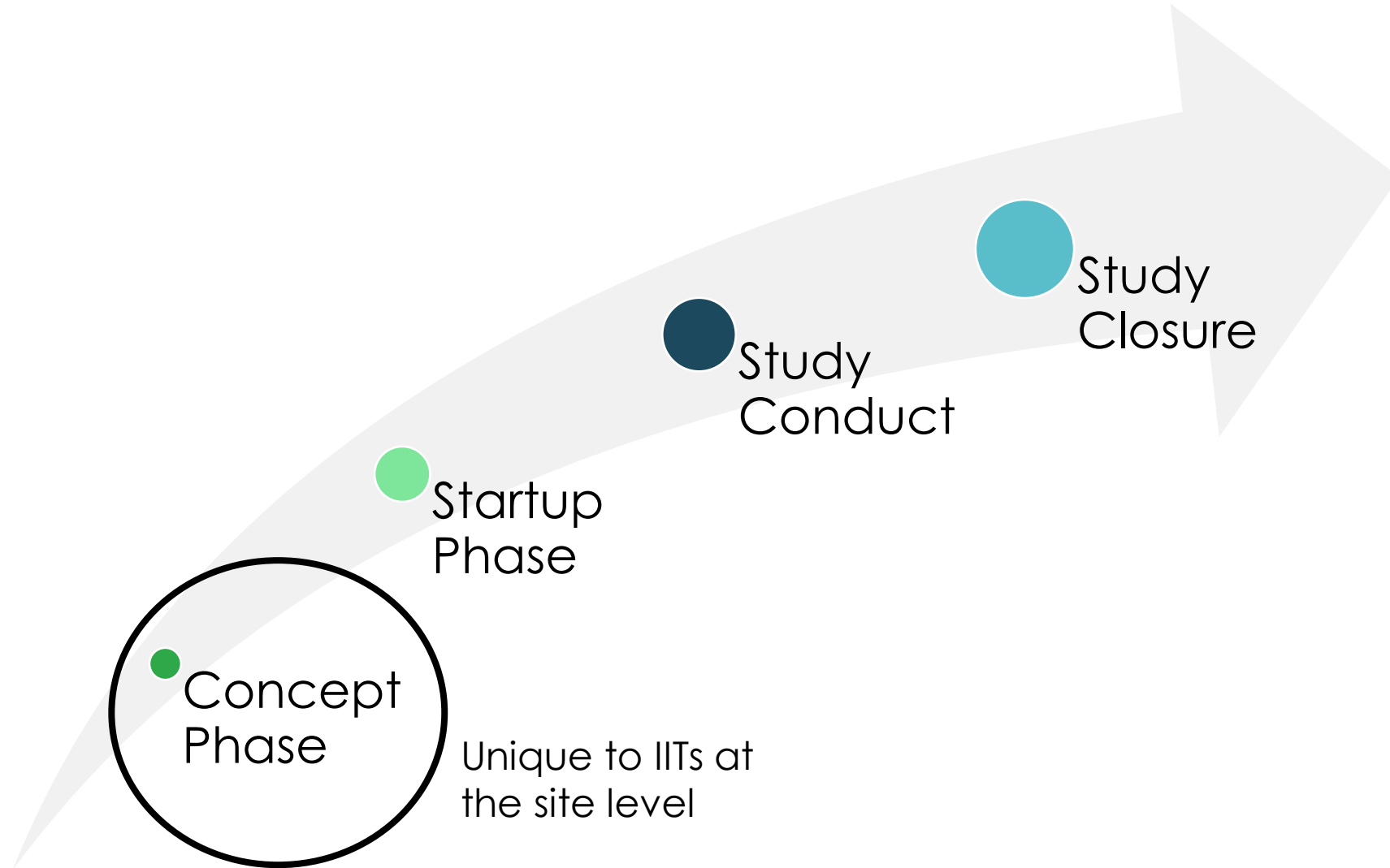


Konwar et al. 2018, *Perspect Clin Res*

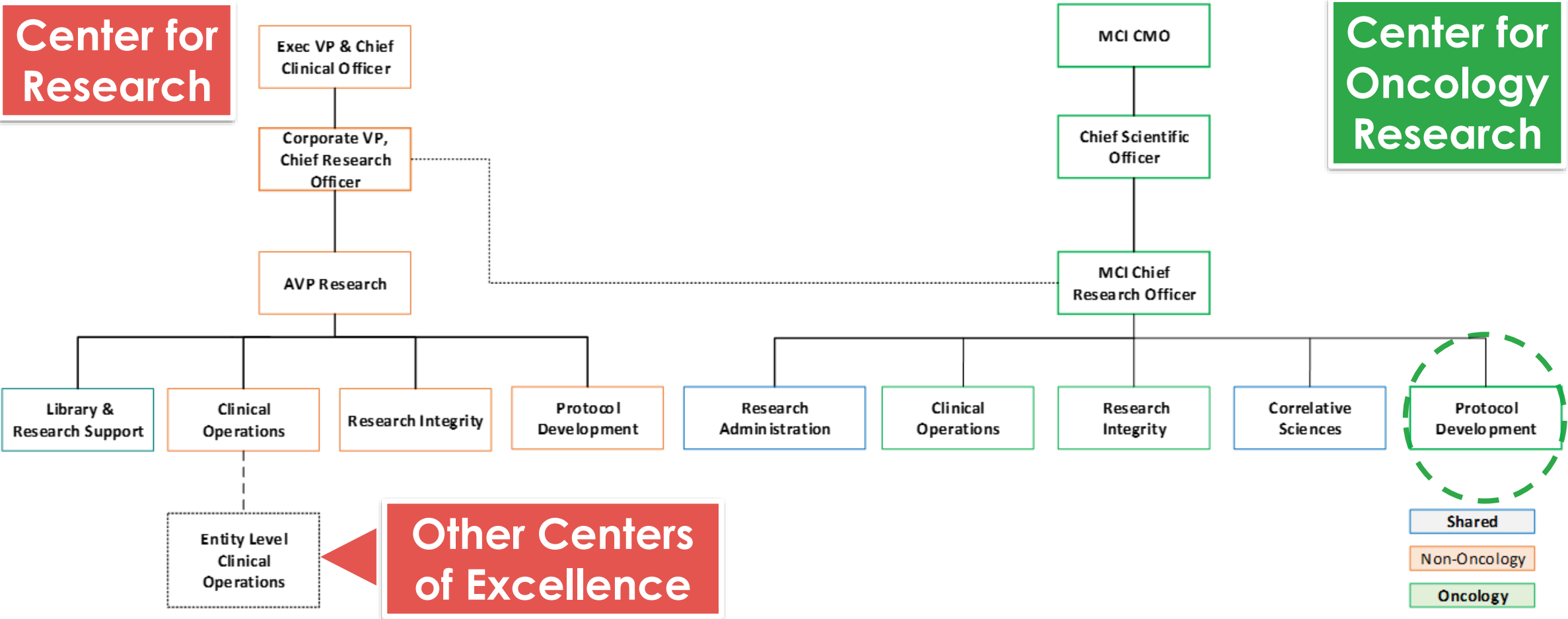
Photo by [National Cancer Institute](#) on [Unsplash](#)



# Investigator-Initiated Study (IIS) Basics



# Baptist Health South Florida Research Enterprise



# Starting from the ground up



Photo by [Markus Spiske](#) on [Unsplash](#)

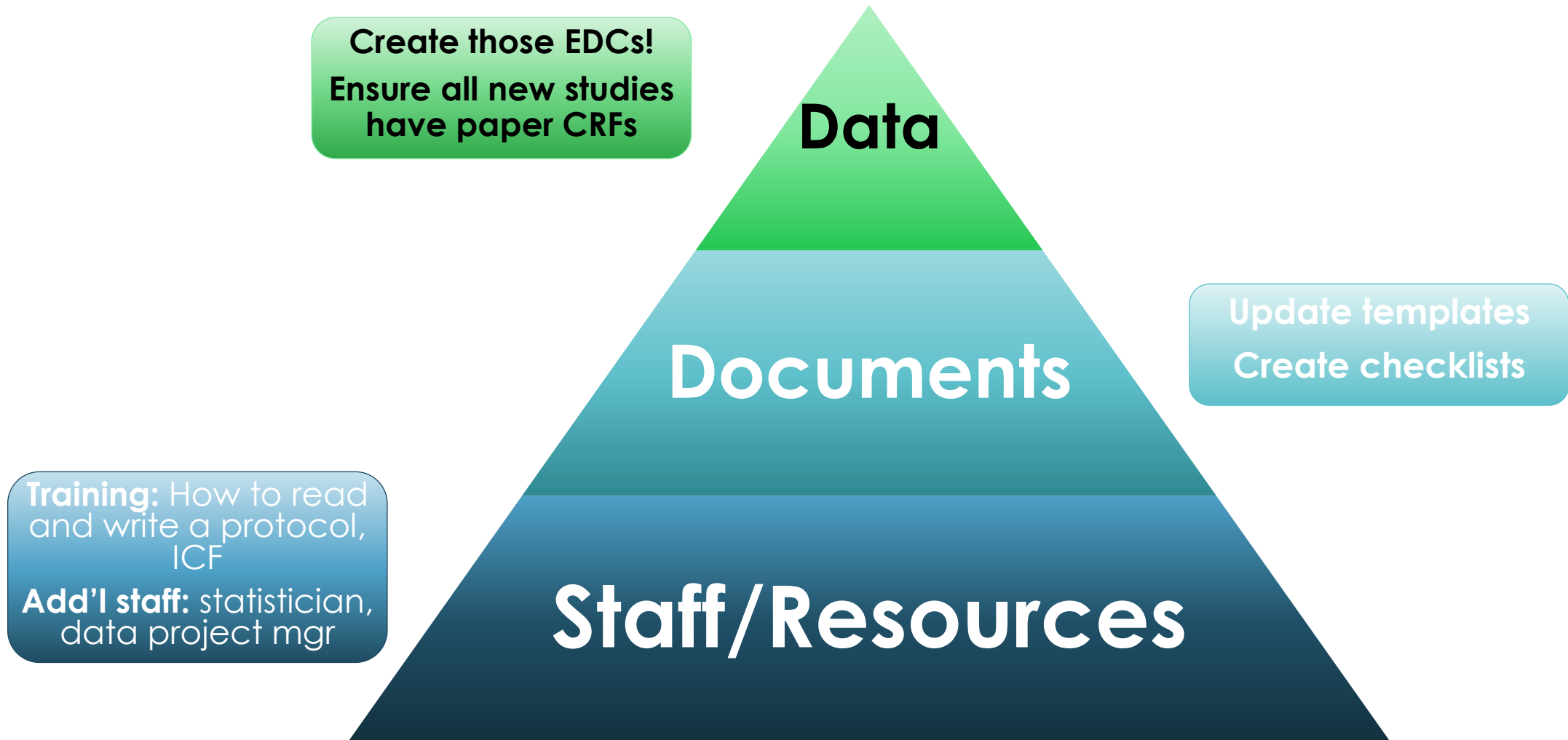
## What did I get myself into?

- ~17 IITs in startup or open; ~5 in development
- Poorly written protocols and ICFs
- Outdated document templates
- No paper CRFs, partially completed EDCs
- One statistician handling all power analyses & sample size calculations, statistical analysis plans, analysis, and data visualization
- Long timelines from concept approved to open to accrual (years in some cases)
- Multiple amendments before a study opened to accrual

**In short...studies that were difficult to operationalize, monitor, and analyze.**



# Starting from the ground up: Needs assessment



# Starting from the ground up: Team Purpose

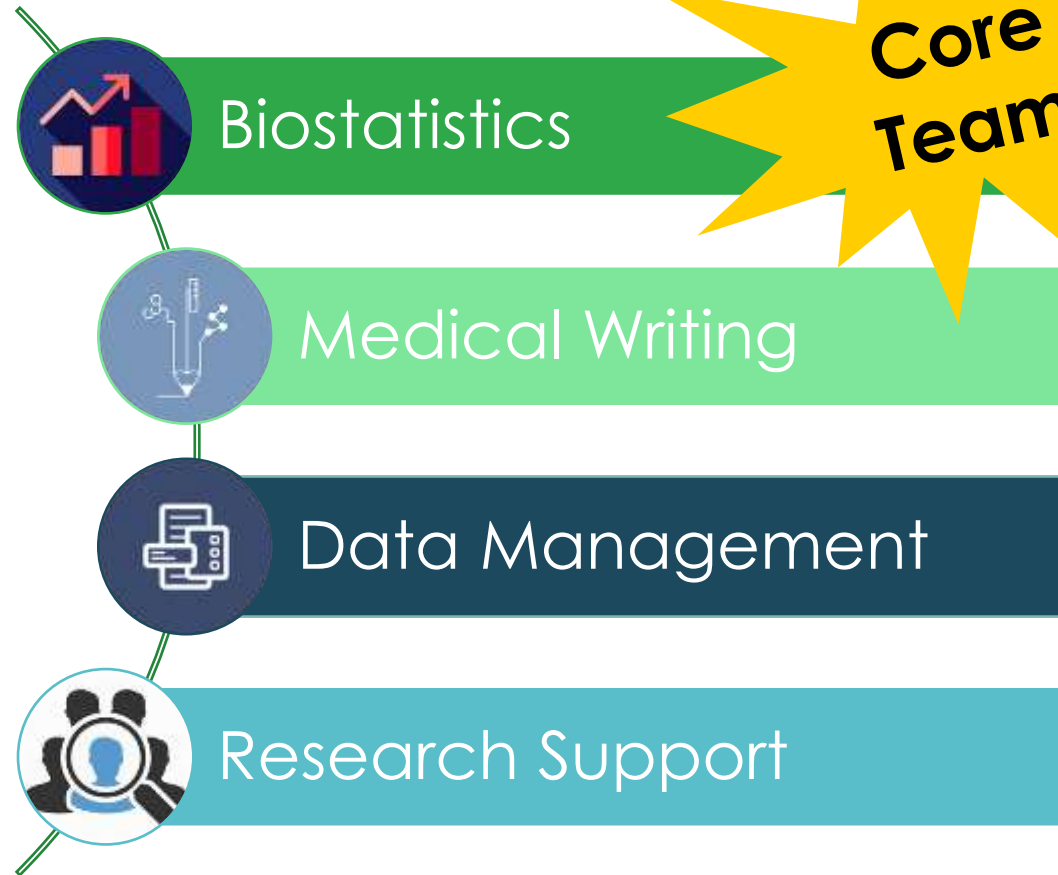
Miami Cancer Institute's Concept Development & Data Management (CDDM) team *partners* with physician investigators to develop their research concepts into *well-designed, well-written scientific protocols* that address an important knowledge gap in the medical literature, with the *ultimate goal* of improving the lives of people with cancer.

CDDM provides a *collaborative environment* and a range of services to take a concept from *ideation through to activation*, and from *data analysis to dissemination*.

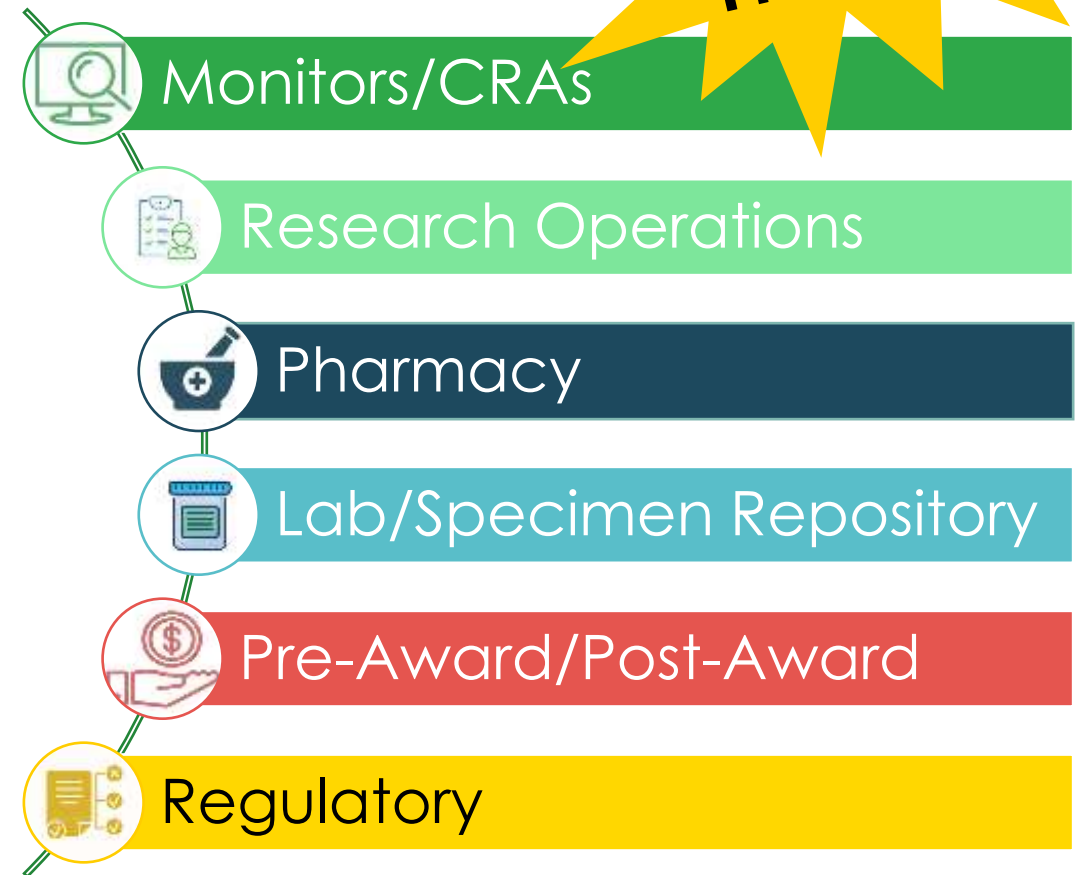




# Who are the key players?



**Miami Cancer Institute's Concept Development & Data Management Team (CDDM)**



**Collaborating Departments**



# Who are the key players? Core Team



## **Biostatistics**

*Ideation:* power analysis/sample size calculation, study design, statistical analysis plan

*Study Conduct:* data, safety, and endpoint monitoring

*Study Results:* data analysis and visualization

*Closure & Dissemination:* abstract, presentation, and manuscript

## **Medical Writing**

*Ideation:* protocol and study document development

*Study Conduct:* protocol amendments and document version control

*Closure & Dissemination:* abstract and manuscript, study reports

*Other:* create templates and training, review/editing of departmental documentation (e.g., policies, SOPs, we content)



# Who are the key players?

## Core Team



### Data Management

*Ideation:* develop paper case report forms (CRFs), and electronic CRFs and data capture systems (eCRFs, EDCs); create data management plans

*Study Conduct:* data management and monitoring, updates/changes to CRFs, eCRFs, and EDCs

*Study Results:* data aggregation, casebooks

### Research Support

Can be research associates/fellows or project managers, for example

Assist investigators with research activities throughout the life cycle such as:

- Literature searches
- Cross-functional team collaboration
- Working on abstracts, presentations, manuscripts
- Keeping track of deadlines



# Who are the key players? Best Friends



## Monitors/CRA's

*Ideation:* review protocol and ICF for appropriate safety and monitoring language; review CRFs and test EDCs to ensure the study can be monitored appropriately

*Study Conduct:* relay issues from monitoring reports that may require amendments to protocol or changes to CRFs/EDC

*Closure:* final monitoring report required before freezing the EDC and downloading casebooks and final study data

## Research Operations

*Ideation:* input into initial protocol development to ensure easy operationalization; review CRFs and test EDCs for data entry

*Study Conduct:* relay when protocol amendments or changes to CRFs/EDC may be required

*Closure:* study closeout, preparation of all final reports, ensuring all study binders and hardcopy patient casebooks are accurate and complete

## Pharmacy

*Ideation:* critical review of protocol for investigational drug receipt, storage, handling, administration, toxicities, drug interactions; create pharmacy manual

*Study Conduct:* may randomize participants



# Who are the key players? Best Friends



## Lab/Specimen Repository

*Ideation:* review of correlative objectives and endpoints in the protocol, provide input for their operationalization, create lab manual

*Study Conduct:* relay when protocol amendments or changes to CRFs/EDC may be required for the lab

*Study Results:* provide any data from correlative studies that may not be captured in the main EDC

## Pre-Award/Post-Award

*Ideation:* grant/funding submission, initial concept budget, full study budget, review of protocol and ICF for appropriate billing and compensation language, coordination with CMS for investigational device coverage

*Closure:* submission of final reports for funding agencies

## Regulatory

*Ideation:* review of protocol and ICF for key regulatory language (e.g., FDA reporting), navigation through committees (e.g., feasibility, scientific review, IRB), FDA submission, CT.gov registration

*Study Conduct:* amendments, interim IRB & FDA submissions, CT.gov updates

*Study Results:* posting results to CT.gov

*Closure:* study closeout, submission of all final reports, ensure regulatory binders are accurate and complete



# Who are the key reviewers and committees?



- Feasibility/Logistics
- Scientific Review
- FDA
- IRB/Ethics
- CMS (for device studies)
- Data Safety & Monitoring



# What are the Key Performance Indicators (KPIs)?

## Productivity & Output

- Total number of requests
- Number/percent of requests that go to startup or are otherwise completed
- Number/percent of abandoned or withdrawn requests
- Number of publications
- Number of abstracts/podium/presentations



## Turnaround Times (TATs)

- Request received to startup or completed
- Request received to abandoned or withdrawn
- Startup to open to accrual

## Other

- Number of amendments between IRB approval and opening



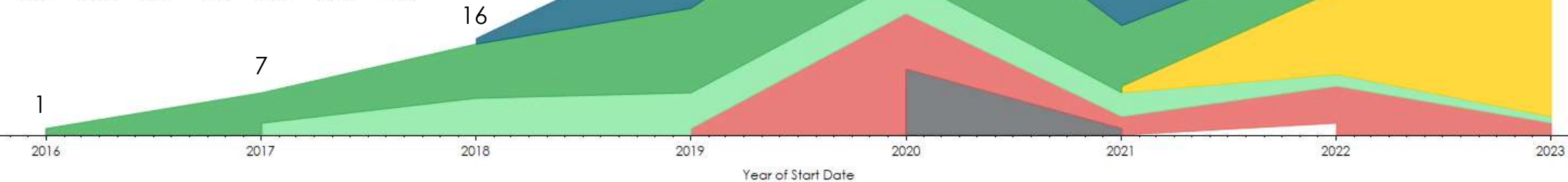
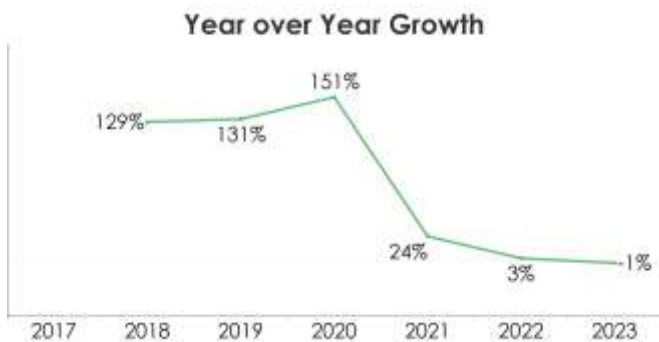
## Data slicing

- Type of requests
- Oncology group
- Principal investigator
- Disease site
- Concept/study phase
- Request date (year/quarter/month)



# Number of Requests by Type & Year

- Other CDDM Support/Request
- Retrospective Chart Review
- Prospective Therapeutic Trial
- Prospective Observational Trial
- Prospective Registry
- Study Amendment
- Banked Specimen Collection
- Prospective Specimen Collection





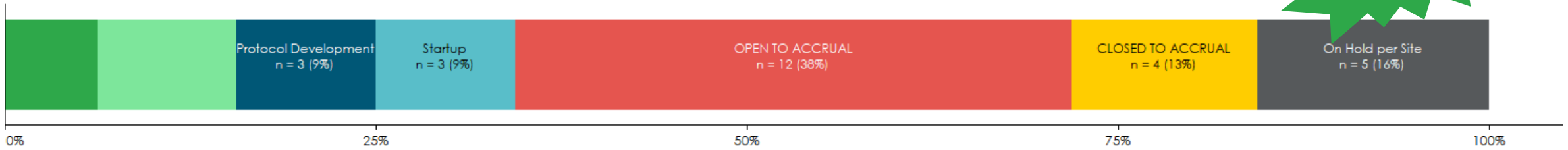
# Requests by Type and Oncology Group (2023 CYTD Sept 25)



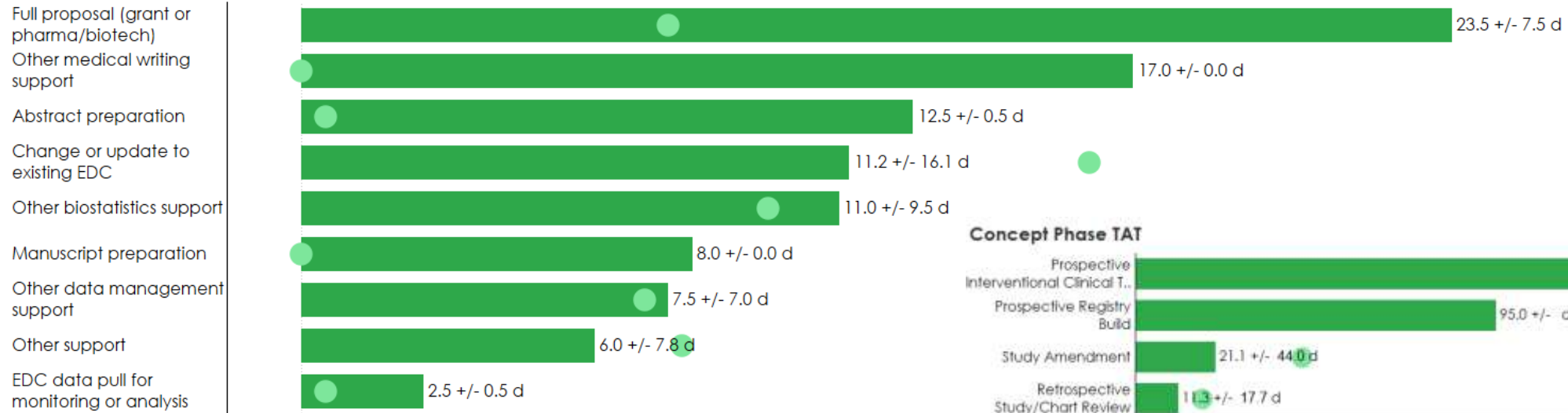
# Study Statuses and TATs

**32 total**

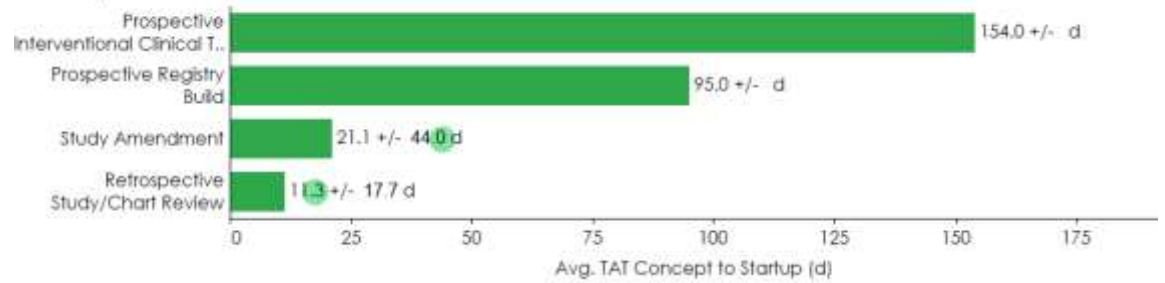
## Prospective Trial Pipeline



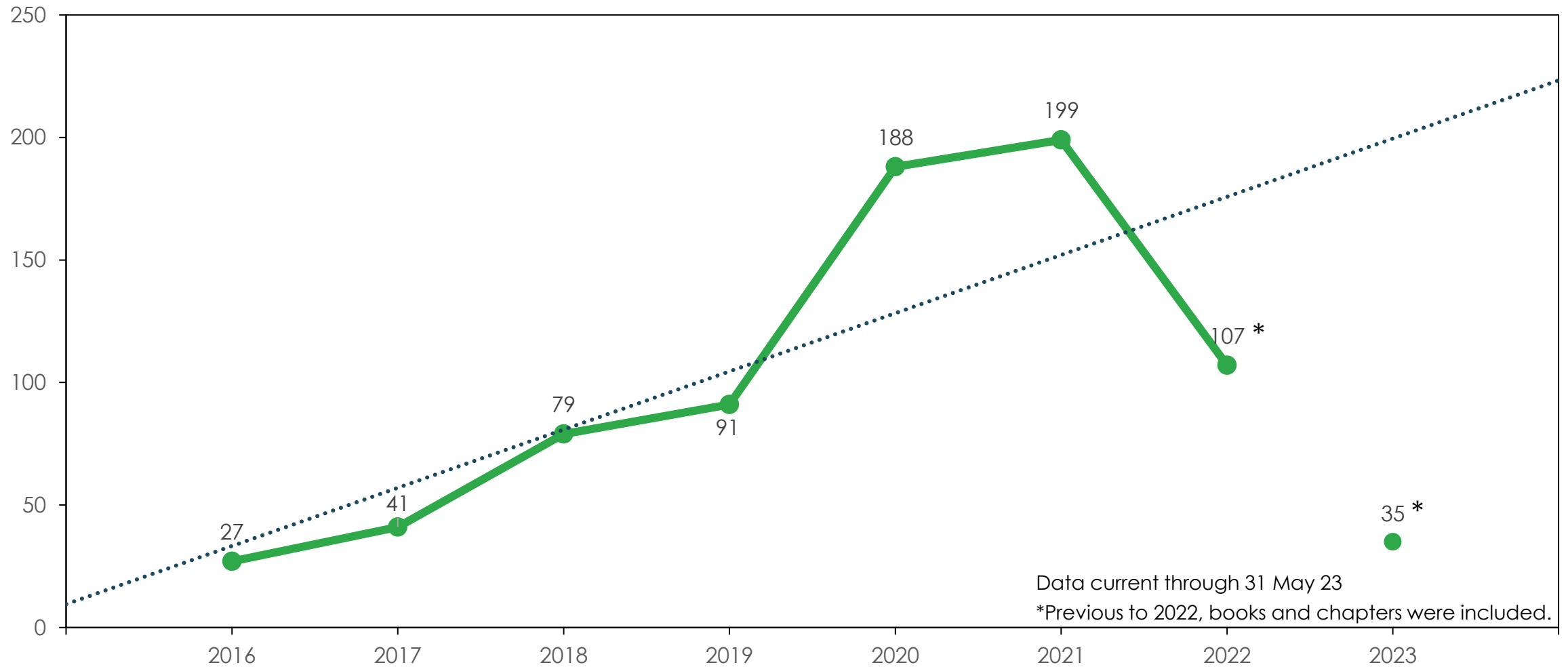
## Request Completed



## Concept Phase TAT



# Scholarly Output: Publications 2016-2023



# What does success look like?

**Engaged PI:** It takes a lot of work to conduct an IIS – PIs who understand the extraordinary time and effort are crucial

**Strong Foundation:** “Core team” and “best friends” help create a solid protocol to ensure smooth operationalization and monitoring

**Meeting TAT Goals:** Having TAT goals and monitoring them regularly will ensure your program is running smoothly

**Minimal Amendments, Safe and Compliant:** Multiple amendments can affect patient safety and compliance, a strong foundation is key

**Contributing to science and medicine:** The ultimate goal is to effect change in practice and clinical care



# Extra tips for success: Intake Form

**Miami Cancer Institute**  
BAPTIST HEALTH SOUTH FLORIDA

**MCI Investigator-Initiated Study Request Form**

Please complete this form to request assistance from the Concept Development & Data Management (CDDM) team, part of the MCI Office of Clinical Research.

Date Form Completed: 07-13-2023

PI First Name: [text box] PI Last Name: [text box]

PI Phone Number: [text box] PI Email Address: [text box]

Is the requestor different from the PI?  Yes  No

**Oncology Group** (\*must select at least one)

- Hematologic Oncology
- Interventional Oncology
- Medical Oncology
- Oral Oncology (formerly Dental)
- Pediatric Oncology
- Radiation Oncology (incl. Physics)
- Surgical Oncology
- Cancer Support (e.g., Psychiatry)
- Other (e.g., Nursing, Pharmacy), specify below

**Management Group** (\*must select at least one)

- Benign Hematology
- Brain & Spine
- Breast
- BMT
- Gastrointestinal
- Genitourinary
- Gynecologic
- Head & Neck
- Malignant Hematology
- Multiple Tumors

**Intake accessible out of network**

Other (e.g., Nursing, Pharmacy), specify below

Malignant Hematology

Multiple Tumors

Skin

Thyroid

Other, specify

Study/Request Type

\* must provide value

Submit

Powered by REDCap

Study Title

\* must provide value

**NEW Prospective Interventional Trial**

Specifically tailored to evaluate direct impacts of treatment or preventive measures on disease.

\*Must use this option for NEW study requests only. If you are requesting an amendment to an existing prospective intervention, use your select "Study Amendment" instead.

**Interventional Clinical Trial Type**

- Phase 0
- Phase I
- Phase I/II
- Phase II
- Phase III
- Phase IV
- Other

\* must provide value

Does this study use a drug, biologic, or device?

Drug **Drug:**

Biologic **Biologic:**

Device **Device:**

None of the above

\* must provide value

Does this project include, or potentially include any of the following?

|  | Yes                   | No                    | Unsure                |       |
|--|-----------------------|-----------------------|-----------------------|-------|
| Inpatient hospital stay<br><small>* must provide value</small>   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | reset |
| Multi-site enrollment or collaboration(s) at any institution(s) outside MCI (e.g., one or more external sites, sub-sites, central lab, etc.)?<br><small>* must provide value</small> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | reset |
| Local labs, central labs, pathology, or specimen banking?<br><small>* must provide value</small>   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | reset |
| Patient-facing questionnaires, surveys, or other similar tools?<br><small>* must provide value</small>   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | reset |

Have you identified a source of funds for this project? If yes, specify.  Yes  No

\* must provide value

Are any other BHSF Centers of Excellence or research areas collaborating on this project?  
\* must provide value

List any collaborators or other individuals working on this project, and their email addresses.

Center for the Advancement of Learning

Center for Women & Infants (CWI)

Graduate Medical Education

Lynn Center Institute (LCI)

Lynn Heart Institute

Lynn Women's Health & Wellness Institute

Marcus Neuroscience Institute (MNI North)

Miami Carolac & Vascular Institute (MCVI)

Miami Neuroscience Institute (MNI South)

Miami Orthopedics & Sports Medicine Institute

Attach one of the following

Click here to download MCI's Protocol Synopsis template\*

\* Must be on BHSF network or VPN to download

\* must provide value

Protocol Synopsis

Other Narrative Project Description/Summary

Submit



# Extra tips for success: Templates and Workflows



CENTER FOR ONCOLOGY RESEARCH

Resources for Investigators:

- **Concept Development and Data Management**
  - Investigator Initiated Research Templates
  - Investigator Initiated Research Workflows
- Expanded Access and Emergency Use

## Concept Development and Data Management (CDDM)

**How to Request Support:**

To request CDDM support for your project, please visit the following link: <https://redcap.link/MCI-CDDM-intake>. You may select a type of study, a study amendment, or select "Other Support" for specific support from one of our cores.

### Investigator Initiated Research Templates

- [Prospective Interventional Clinical Trial Protocol](#)
- [Prospective Interventional Clinical Trial Synopsis](#)
- [Prospective Observational Clinical Trial Protocol](#)
- [Prospective Clinical Trial Informed Consent Form](#)

- [Prospective Biospecimen Collection Protocol Template](#)
- [Prospective Registry Protocol Template](#)
- [Prospective Registry Informed Consent Form](#)
- [Retrospective Manual Chart Review Protocol Template](#)
- [Retrospective MCI Data Repository Protocol Template](#)
- [Retrospective Data Collection Sheet Template](#)
- [Retrospective Data Linkage Log Template](#)
- [National Cancer Database \(NCDB\) Participant User File \(PUF\) Request Template](#)

### Investigator Initiated Research Workflows

- [Prospective Interventional IIS Concepts Phase](#)
- [National Cancer Database \(NCDB\) Participant User File \(PUF\)](#)

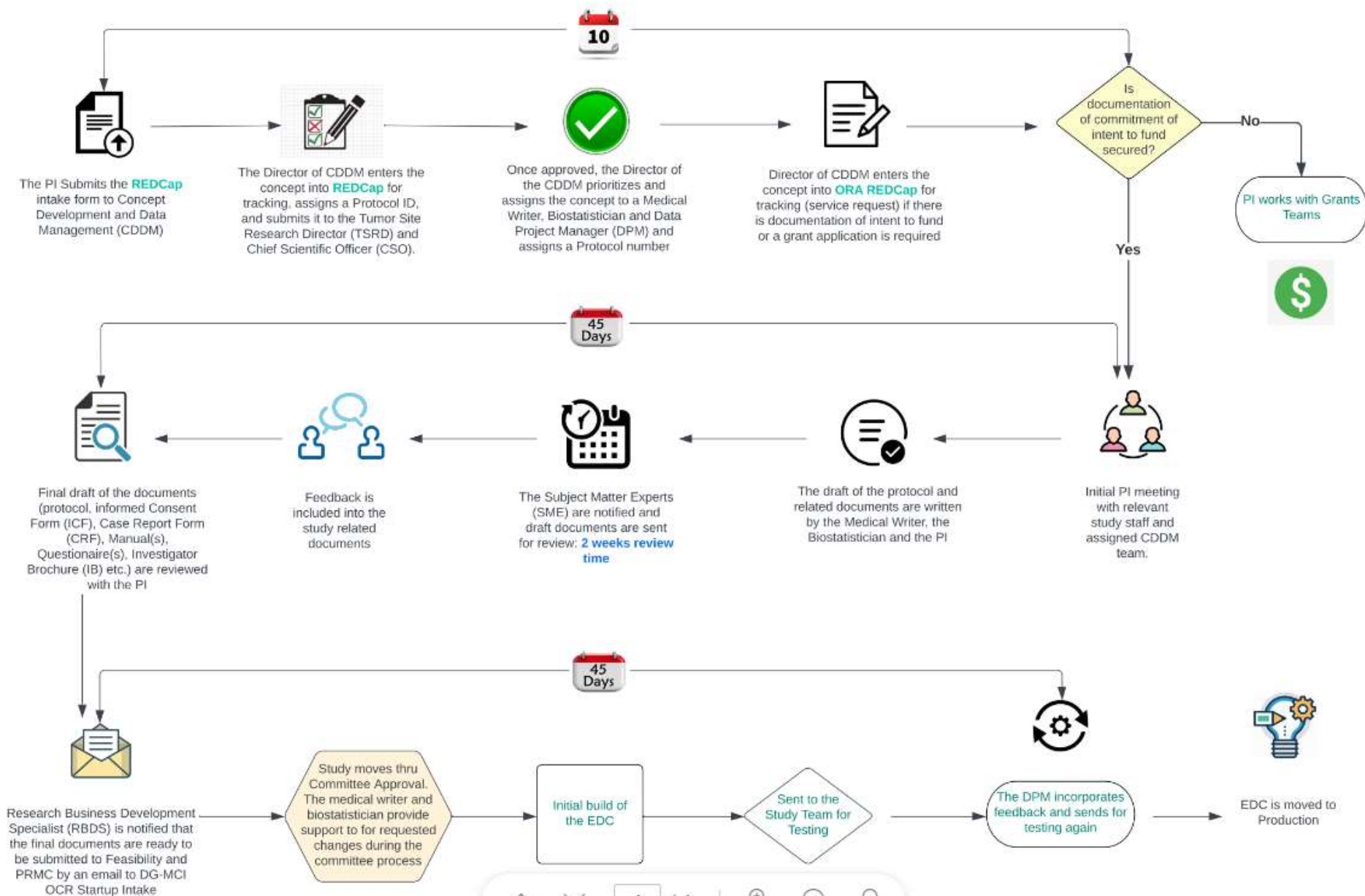
**Other Resources:**

[NIH/FDA Electronic Protocol Writing Tool](#)

Available  
on  
Intranet



## Prospective Interventional IIS Concepts Phase



## Example Workflow

# Extra tips for success: TAT Tracker

**Time Tracker**

Date submitted to CDDM: 07-10-2023

Date request received by registrar (Also be sure to create folder in share drive): 07-11-2023

Does request require approval or acknowledgement from Chief Research Officer, Chief Scientific Officer, Oncology Group Chief, or Department Director?  Yes  No

If yes, select:

Chief Research Officer  Chief Scientific Officer  Oncology Group Chief  Department Director

**Chief Research Officer**  
Date Sent for Approval/Acknowl: 07-10-2023  
Date Approval/Acknowl Received: 07-10-2023

**Chief Scientific Officer**  
Date Sent for Approval/Acknowl: 07-10-2023  
Date Approval/Acknowl Received: 07-10-2023

**Oncology Group Chief**  
Date Sent for Approval/Acknowl: 07-10-2023  
Date Approval/Acknowl Received: 07-10-2023

**Department Director**  
Date Sent for Approval/Acknowl:   
Date Approval/Acknowl Received:

Date study assigned to CDDM team:   
Date of initial concept meeting with PI and study team:   
Submission to ORA:  Yes  No  
Budget/Contract: 07-11-2023  
Questionnaires:   
First Drafts Complete:  
Protocol:   
ICF:

**Drafts Reviewed by Funding Agency**

Sent to agency:   
Received back:   
Date documents sent to SME for review:   
Date documents sent to Startup/Regulatory:   
Committee Reviews:  
Feasibility:   
PRMC:   
Date of first review:   
Date of approval:   
Number of drafts by PRMC approval:  
Protocol:   
ICF:   
Data Management - EDC Creation or Update Required:  Yes  No  
Date DMP draft complete:   
Date EDC build/update started:   
Date EDC build/update complete:   
If applicable:  
Date on hold/pending documents:   
Date off hold/documents received:



Notes to add about process, potential delays, etc.   
Study Status: **\*\*Be sure to change this status as applicable!\*\***  
Form Status:   
Complete?   
Abandoned  
Concept Development  
Concept Submitted/Pending Funding Decision  
Declined - Funding Agency  
Declined - PI/PIB  
On Hold per Site  
Pending Documents  
Protocol Development  
Startup  
Request in Process  
Request Complete  
Withdrawn  
NOTE: To delete the entire record off form/portal, see the record action drop-down at top of the Record Home Page.







# Extra tips for success: Medical Writing Checklist for Protocols & ICFs

## Scientific Review

Is the protocol written to address the research question(s) and hypothesis(es)?

- Relevant background
- Rationale
- Study design (# arms, placebo or comparative tx, length of follow-up, randomization, schematic, etc.)
- Objectives with matching endpoints (and associated timeframe – important for CT.gov)
- Sample size
- Study population and eligibility
- Study intervention (incl. how many doses/cycles can be missed and still be valid)
- Tests and assessments (specify tests in each lab panels, assessment frequency, duration)
- Correlatives (type, when, how, which lab)
- Statistical analysis

## Human Subjects Protection

- Is the risk of harms contrasted to probability of benefits?
- Explanation of risks/benefits in protocol and in informed consent form
- AEs, SAEs, and UPs
  - General definition, protocol-specific
  - Protocol-specific time points for collection
  - Protocol-specific reporting instructions and to whom (e.g., IRB, funding agency, regulatory agencies)
- Protocol and ICF clearly state which activities are standard care vs. research, by study visit?
- Privacy and confidentiality information is included
- ICF written in 6th to 8th grade language – check samples of you text in a readability calculator (bullet points help with improving readability)





# Extra tips for success: Medical Writing Checklist for Protocols & ICFs

## Completeness

- Include all abbreviations from the document in the abbreviation table
- PI signature page is included; for multi-site, site PI signature page included
- Are required sections included according to the protocol and ICF templates?
- Are multiple consent forms required? e.g., pregnancy, pregnant partner, child assent, LAR, etc.
- If pharmacy or lab manuals are required, have they been completed by their respective teams?
- If questionnaires or surveys are required, have licenses been requested through ORA?
- If participant diaries are required, have the templates been completed?
- Information about monitoring, privacy and confidentiality is included

## Formatting

- Tables fit within margins
- Tables and figures are clear and appropriately sized (not blurry, stretched, smushed, i.e., use high-res, keep aspect ratio locked)
- Table and figure captions are used; figure & table list included after table of contents
- Linked cross-references as needed throughout
- Consistent fonts, sizes, line spacing throughout

## Personnel, Sites, and Collaborators

- Co-I/Co-PI requires a separate 1572
- If a Co-I or Sub-I is at another institution, what research activities will be taking place at that institution? Do they need to have their own IRB approval or will one IRB cover their work?
- Special considerations for multi-site studies





# Extra tips for success: Medical Writing Checklist for Protocols & ICFs

## Consistency

Protocol consistent throughout entire document.  
Ensure consistency after each revision.

- Version number and dates on title page match page headers and file name
- Synopsis matches relevant protocol sections
- Study design schematic matches text
- Schedule of Activities matches Dosing and Administration, Study Assessments and Procedures, Safety and Other Assessments
- Protocol sections for Dosing and Administration, Preparation/Handling/Storage/ Accountability, Concomitant Therapy match the pharmacy manual
- Study endpoints included in Statistical Analysis Plan
- Double check titles of all tools/QOLs/assessments are correct and consistent throughout
- Update the Table of Contents with each update

Reference consistency – consider using a reference manager like EndNote

- All references cited in the text are listed in the reference section
- All references listed in the reference section are cited in the text
- Include PubMed ID (PMID) for ease with registering the trial on ClinicalTrials.gov

## Cross-document consistency

- Protocol synopsis matches ICF summary
- Schedule of events in protocol matches in ICF
- Protocol drug dosing and administration section matches pharmacy manual
- Protocol correlative section matches lab manual
- Titles of tools/QOLs/assessments match across documents



# Takeaways

## No matter what your program looks like currently...

- First, start with your people and your resources
- Next, build your foundation of a solid protocol and consent form
  - Remember your best friends plus your core team
  - Use the various committees to improve your product before IRB approval
- KPIs help keep track of your final product
  - Overall volume, TATs, amendments before opening
- Marker of success: Contributing to science and medicine through dissemination and practice change
- Tips for success: Workflows, templates, checklists



# Thank You.

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