Clinical & Translational Science Institute

Research Professionals Network Workshop Series

MANAGING A MULTICENTER TRIAL

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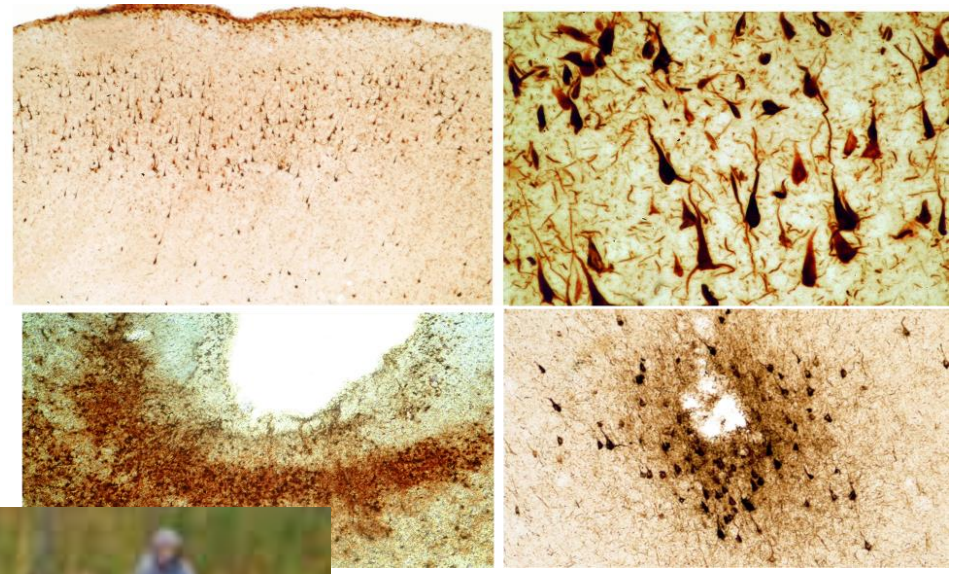
DIAGNOSE CTE
Research Project

Diagnostics, Imaging, And Genetics
Network for the Objective Study and Evaluation of
Chronic Traumatic Encephalopathy

- 7-year Longitudinal Trial
- Enrolling:
  - Former NFL Football players
  - Former College Football players
  - Controls



- 3 Day Baseline Visit, including:
  - 2 PET Scans
  - MRI Scan
  - Lumbar Puncture
  - Neuropsychological testing
  - Neurological testing
  - Medical history
- 3-year follow-up Visit

The DIAGNOSE CTE Team

Four Project PIs:

Eric Reiman, MD, Martha Shenton, PhD, Robert Stern, PhD, Jeffery Cummings, MD

Four Enrollment Sites:

BOSTON UNIVERSITY SCHOOL of Medicine

Cleveland Clinic

MAYO CLINIC

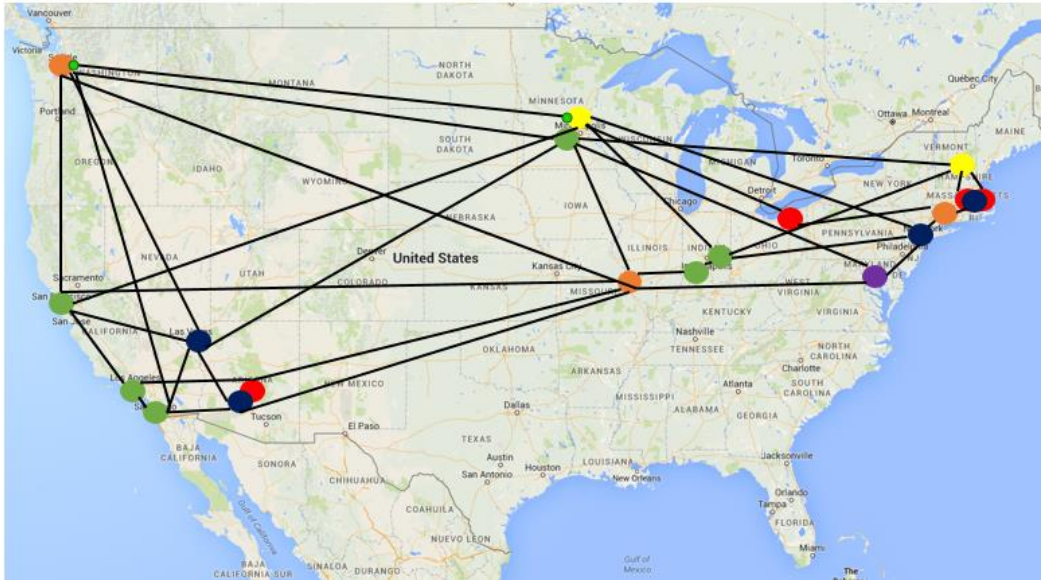
NYU School of Medicine
NYU LANGONE MEDICAL CENTER

Four Site PIs:

Robert Stern, PhD, Laura Balcer, MD, Charles Bernick, MD, Charles Adler, MD, PhD

That’s not all….

30+ Additional Investigators from all over the country:



Multiple Collaborating Institutions:

BWH BRIGHAM AND WOMEN’S HOSPITAL

Banner Alzheimer’s Institute

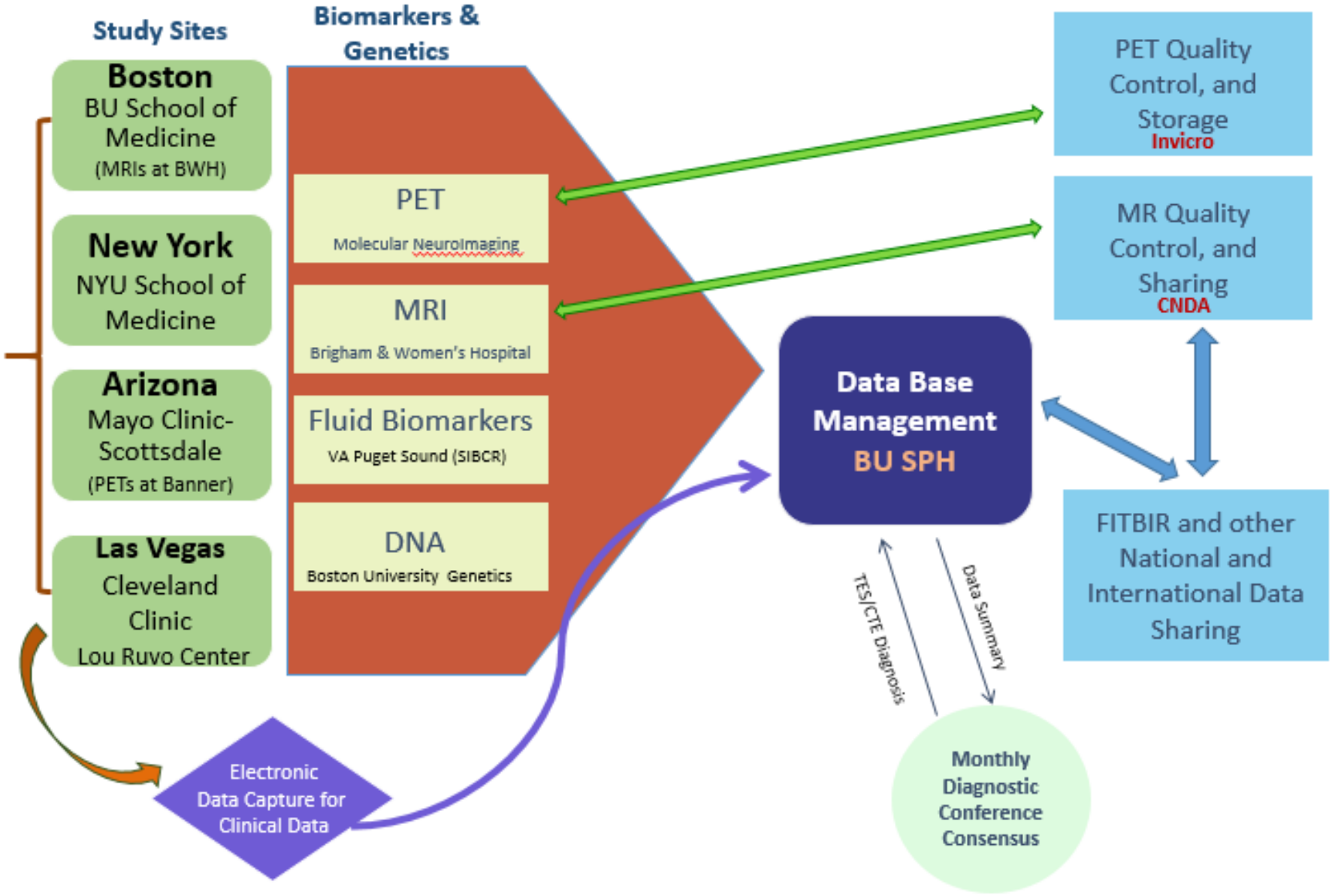
BOSTON UNIVERSITY SCHOOL of Public Health

NRG Neuroinformatics Research Group

UW Medicine SCHOOL OF MEDICINE

Invicro

Coordinating Center



Falling Into The Abyss

Starting a Multicenter Trial:

1. Review the federal and Institutional Regulations that the study must meet
2. Give yourself TIME!
3. Create a time-line
4. Ask questions and use your resources
5. Learn the ICH GCP Principles for sponsors

*Advice provided by Fiona Rice, previous Project Manager

Managing a Multicenter Trial

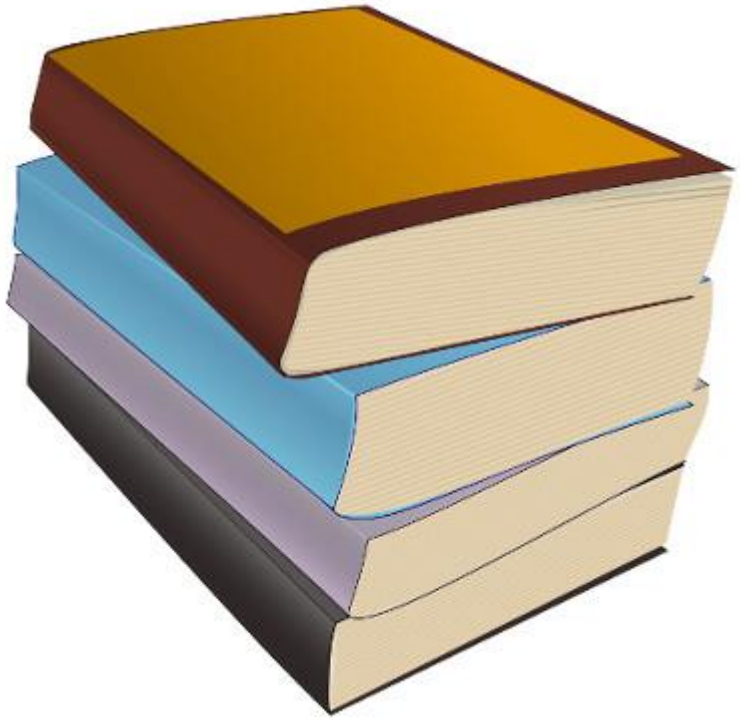
- Managing Personnel
- Quality Assurance
- Safety and Risk Evaluation
- Monitoring and Auditing
- Documentation
- Regulatory Maintenance
- Data Management
- Communication
- Participant Recruitment
- Website/Social Media Management
- Financial Management
- IND Management

Managing The Team

- Start-up:
  - Selecting Investigators
  - Selecting qualified medical personnel
  - Selecting sites
- Training
- Creating the protocol
- Allocation of responsibilities
- Tracking staff certifications

Quality Assurance

- Ensure that all sites are following the protocol
- Create SOPs or manuals for different aspects of the study
  - Examples:
    - Electronic data collection
    - Neuropsychological testing
    - Imaging
    - Biofluids collection
- Certifications
  - Confirm that all investigators and staff are qualified to be a part of the study
  - Train and approve staff members to conduct enrollment visits



Safety & Risk Evaluation:

This is for both the study participants and the staff

- Procedural safety plans for all study activities
- Ensuring that the participant is aware of all risks
- Creating guidelines and procedures for reporting Adverse Events at each site
- Reporting of all Adverse Events, Serious Adverse Events, and Unanticipated problems to the appropriate regulatory authorities
- Creating safety plans for study coordinators and other staff in the event they feel unsafe

Monitoring

- Site Visits:
  - Visit each site on a yearly basis (sometimes more)
  - Evaluate compliance and conduct of the study
  - Review EVERYTHING
    - Consent Forms
    - Participant Binders
    - Regulatory Binders
    - Electronic Data
  - Gain an understanding of how each site works
  - Document everything and create a report

Example of Site Visit Report

DIAGNOSE CTE Research Project, NYU Quality Assurance Review
Date: 08/03/2017 – 08/04/2017
Review conducted by: Courtney Diamond, Project Manager & Megan Mariani, Research Assistant
Met with: Lisena Hasanaj, Liliana Serrano, Dr. Balcer, Dr. Barr, Dr. Fazl, Dr. Lord, MRI Team, PET Team, and Lab team

Database and Tracking:

Database and Tracking Findings	Action Item	Date Completed	NOTES
Neuropsych scores need to be entered into REDCap A2-Diagnose CTE- DOUBLE DATA ENTRY Project		Completed by:	
Florbetapir and AV-1451 tracking forms		Completed by:	
Consent form dates		Completed by:	

Documentation:

What do you need to document? Short answer, **Everything!**

- CVs
- Training logs
- Certifications
- Audit/Monitoring Reports
- Regulatory approvals
- IRB Amendments
- Consent forms
- Meeting notes
- AEs/SAEs/Ups
- Correspondence

Why?

Managing Regulatory Authorities

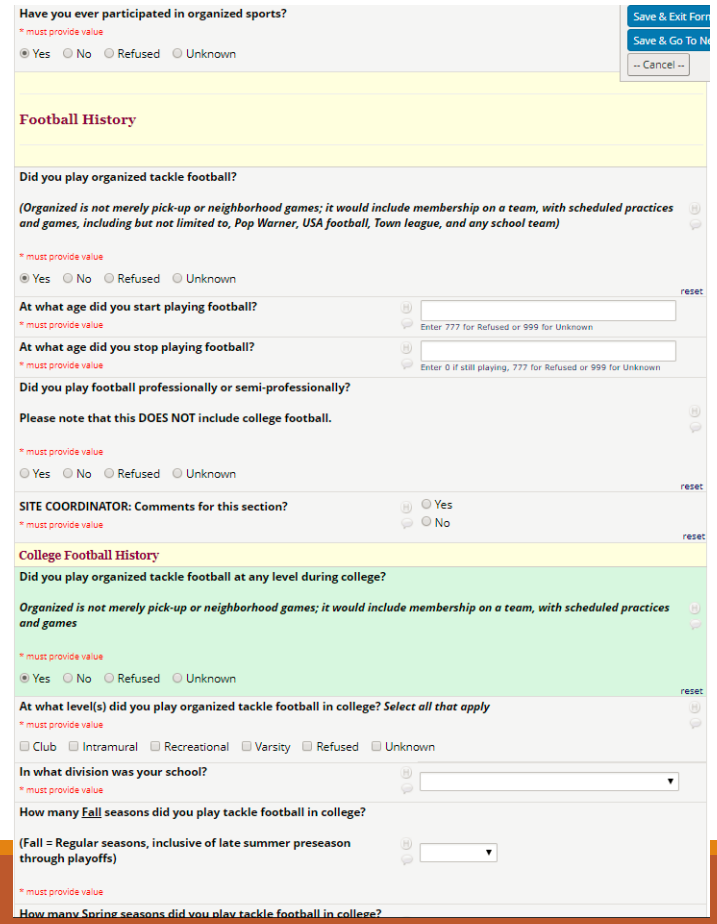
- Site IRBs:
  - Boston University Local IRB
  - NYU Local IRB
  - Mayo Local IRB
  - Cleveland Clinic Local IRB
  - Banner WIRB
  - BWH Local IRB
- Other Regulatory Aspects:
  - FDA
  - IND Reporting
  - NIH Reporting
  - Clinicaltrials.gov

Data Management:

Get yourself a good data team!

- Create a secure database
- Create a tracking database
- Track enrollment visits
- Run reports
- Audit the data
- Uploading data to FITBIR

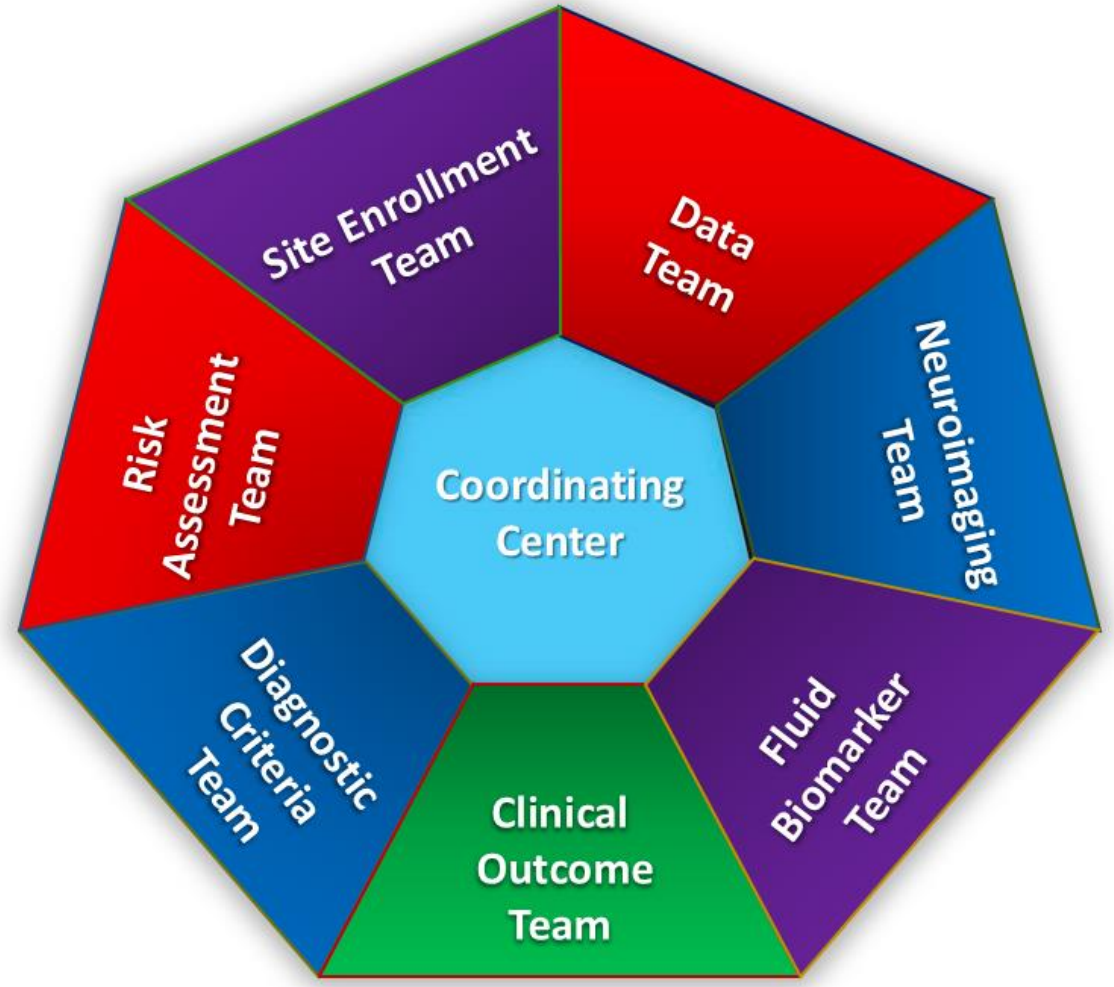
Data Collection Database (REDCap)



Communication:

- Schedule Meetings:
  - Weekly Coordinator Meetings
  - Weekly Imaging Site Meetings
  - Weekly Data Team Meetings
  - Weekly Coordinating Center Meetings
  - Monthly Neuroimaging Meetings
  - Monthly Biofluids Meetings
  - Monthly PI Meeting
  - Quarterly Executive Committee Meetings
  - Advisory Board Meetings
  - Annual Investigator Meetings

Keep Open Lines of Communication!



Site Awareness:

1. The Problem Child (Rogue Site)

2. Ensuring that everyone has the same protocol and informed consent forms

3. Submitting and tracking Adverse Events

4. Trainings

5. Keeping open communication from across the country

6. Time differences

You have to always be available for each site and try to split your time equally!

Site Perspective:

- Understanding:
  - Why the sponsor is asking for so much documentation
  - Why so many meetings need to be scheduled
  - Why the sponsor needs to conduct site visits
- Ask Questions
- Utilize your resources:
  - IRB Personnel
  - CRRO
  - PI
  - Sponsor Site (Coordinating Center)
- Review ICH GCP Guidelines

It’s All A Balancing Act

Thank you!

Questions!