Needs Assessment for a Clinical Trials Management System

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Principal Investigator
IRB MS1
CareConnect
ePass
Financial Disclosure
PI Exemption
Pharmacy Application
Radiology Application
MRSC Application
clinicaltrials.gov
CTRC Application
FDA 1572
EDGE
Subject Payment request
SAE/AE report
Clinical Lab request
Release of information form
NIH Inclusion Enrollment Report

Protocol Title
IRB MS1
CareConnect
ePass
Financial Disclosure
PI Exemption
Pharmacy Application
Radiology Application
MRSC Application
clinicaltrials.gov
CTRC Application
FDA 1572
Subject Payment request
SAE/AE report
Clinical Lab request

Coordinator Contact Information
IRB MS1
CareConnect
ePass
Pharmacy Application
Radiology Application
MRSC Application
clinicaltrials.gov
CTRC Application
Subject Payment request
Release of information form
How many times do you enter the same information?
Clinical Studies

Clinical Trials
  - PI Initiated
  - Industry Sponsored

Clinical Research
  - Federal, State and Non-Profit funding

Preclinical studies
What’s the difference between a Clinical Study, a Clinical Trial and Clinical Research?
Clinical Studies

What’s the difference between clinical studies and clinical research?

It depends who is asking the question.

Clinical Studies

Preclinical studies

Clinical Research
## Functions of a CTMS

### Protocol & Site
- Subject
- Visit

### Other Data Capture

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### Clinical Trial Management System Functionality

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CTMS Functions

- Enter Protocol and Sponsor Information
- Enter or Transfer Study Team Information
- Staff Credentials & Qualifications
- Qualifying Clinical Trial Assessment
- Medicare Coverage Analysis
- Internal Cost Budget
- Sponsor-Negotiated Budget
- Create Event Visit Grid
Subject Functions
Visit Functions
Other Data Capture Functions
Please complete the questionnaire
Include your email for a chance to win a $75 gift card