
Regulatory Support Office (RSO)
Human Research Protection Program

Regulatory Support Office (RSO)

ClinicalTrials.gov Reporting Support Program

Assist **Responsible Party** (Principal Investigator) with ClinicalTrials.gov Reporting

- Registration
- Updates
- Results

FDA Submission Support Program

Assist **Sponsor Investigator** with FDA submissions for IND IDE, Expanded Access

- Preparation
- Submission
- Maintenance

Resource & Education

RSO Website

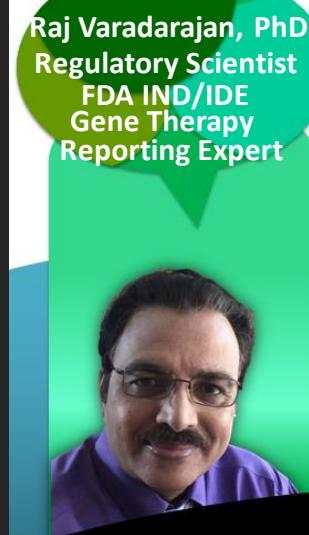
- Application templates
- Quick guidance documents
- Decision trees
- Educational video library

Regulatory Education

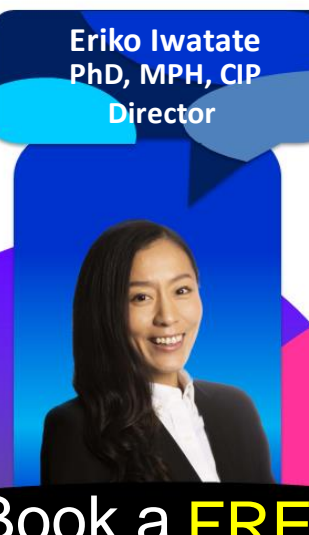
- Best practice training
- Consultation via Booking

We are here to help

Visit Regulatory Support Office Website



Raj Varadarajan, PhD
 Regulatory Scientist
 FDA IND/IDE
 Gene Therapy
 Reporting Expert



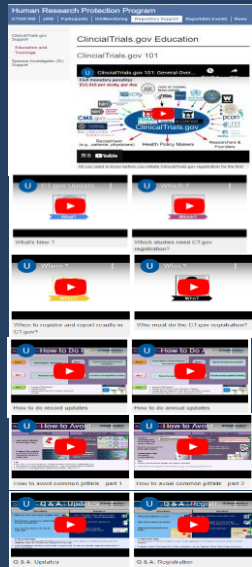
Eriko Iwatate
 PhD, MPH, CIP
 Director



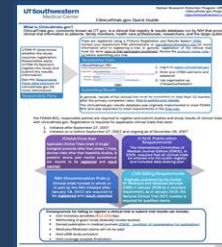
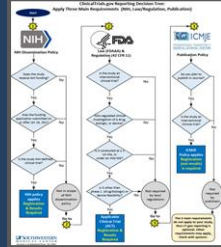
Rasija Nambiar
 MSc, PGDPM
 Regulatory Scientist
 ClinicalTrials.gov &
 FDA Expanded Access
 Reporting Expert

Book a **FREE** consultation with us!

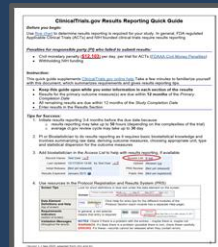
Selected Resources for ClinicalTrials.gov Support



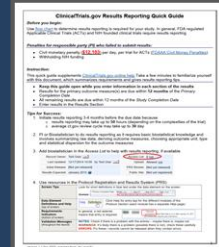
CT.gov Decision Tree



Quick CT.gov Guide

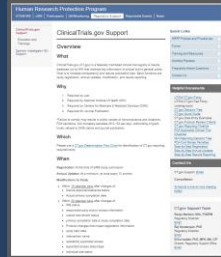


Step-by-step Registration



Step-by-step Results

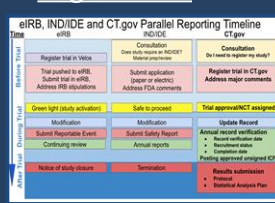
CT.gov Video Library



Website



CT.gov Guide for NIH Funded Trial

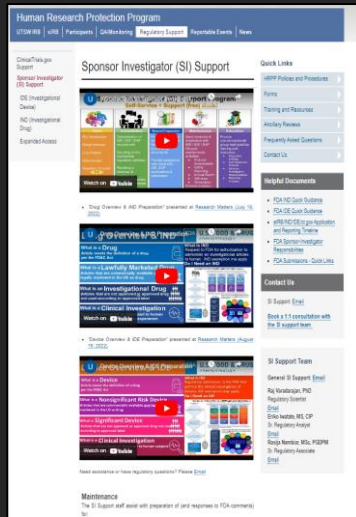


Reporting Timeline



ClinicalTrials.gov Consultation Booking

Selected Resources for Sponsor Investigator FDA Support



FDA IND/IDE/EA Video Library



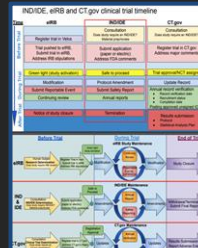
EA Quick Guide



IND Quick Guide



IDE Quick Guide



Timeline



Website



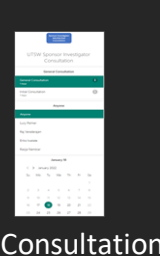
EA Step-by-Step



SI Responsibilities



Templates



SI-Consultation Booking