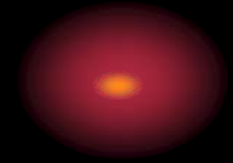


# ONCOLOGY CLINICAL TRIALS



## PITFALLS AND OPERATIONAL ISSUES



**Dr Allana Hemus**

**University of the Witwatersrand - Oncology**



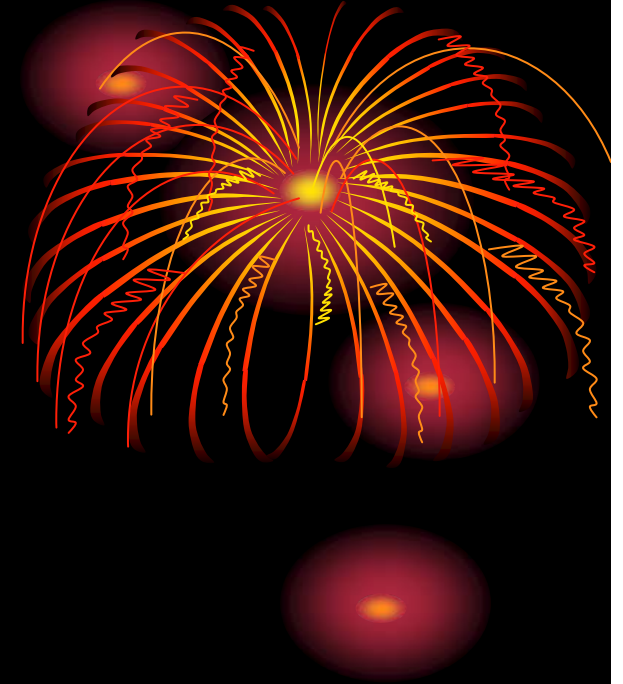
❖ **RADIOLOGY**

❖ **PRE-PLANNING AND  
STUDY SET-UP**

❖ **STUDY SUPPLIES**

❖ **QUERIES**

❖ **TEAMWORK**

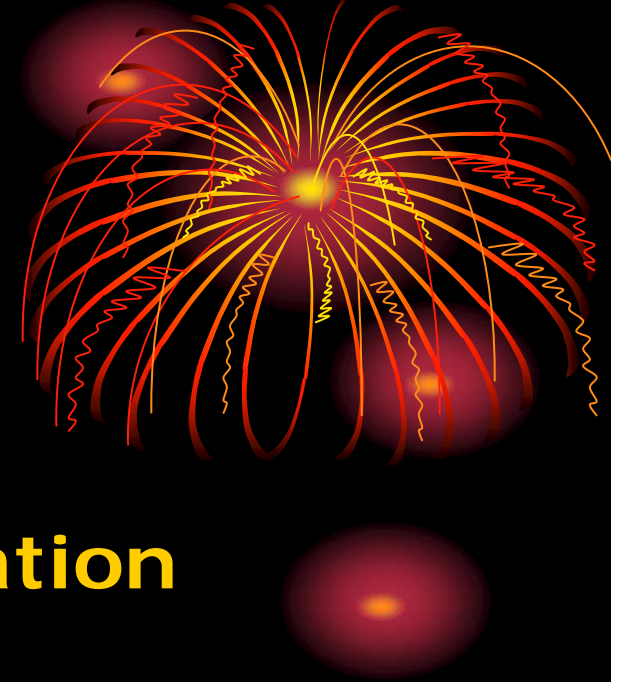


# RADIOLOGY

- ❖ **Assessment of Primary and Secondary Objectives**
- ❖ **Radiology Set-Up**
  - \* **Training**
  - \* **Supplies**
  - \* **Contract**
- ❖ **Costs**
  - \* **Overseas vs Local**
  - \* **Negotiate Prices**



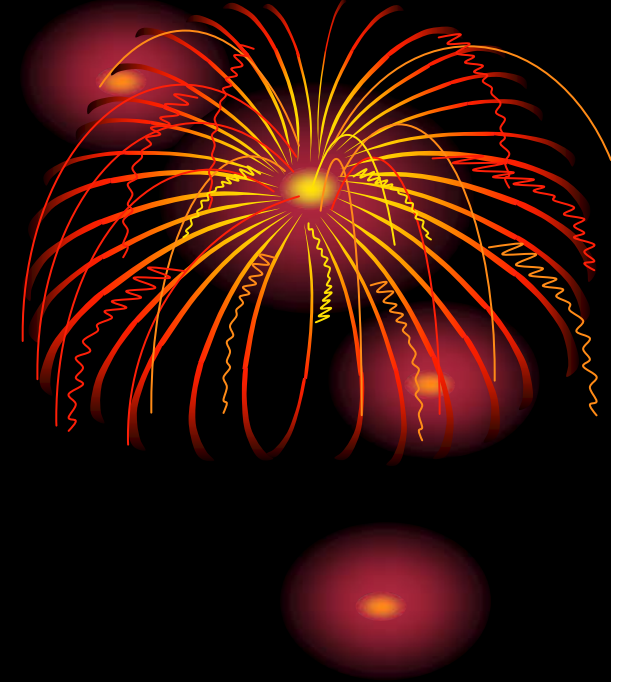
# PRE-SCREENING & STUDY SET-UP



- ❖ Pre-planning over 2 – 3 visits prior to study initiation
- ❖ CRF – training and source document compilation
- ❖ Frequently encountered problems
- ❖ Full-Time study staff
  - \* Administrative
  - \* Logistics



# PRE-PLANNING & STUDY SET-UP



## ❖ BUDGET

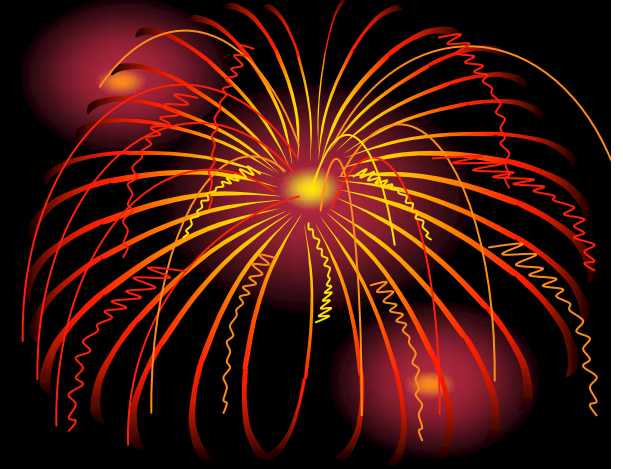
- \* Study Visit Schedule
- \* Unscheduled Visits
- \* Screen Failures
- \* Patient Transport
- \* Visits over 2 days

## ❖ SIV – Medical and Final Overview

## ❖ FIRST PATIENT – First Visit



# STUDY SUPPLIES



- ❖ **ADDRESSED CORRECTLY**
- ❖ **LABELLED WITH STUDY TITLE/NUMBER**
- ❖ **NOTIFICATION OF ARRIVAL**



# STUDY SUPPLIES

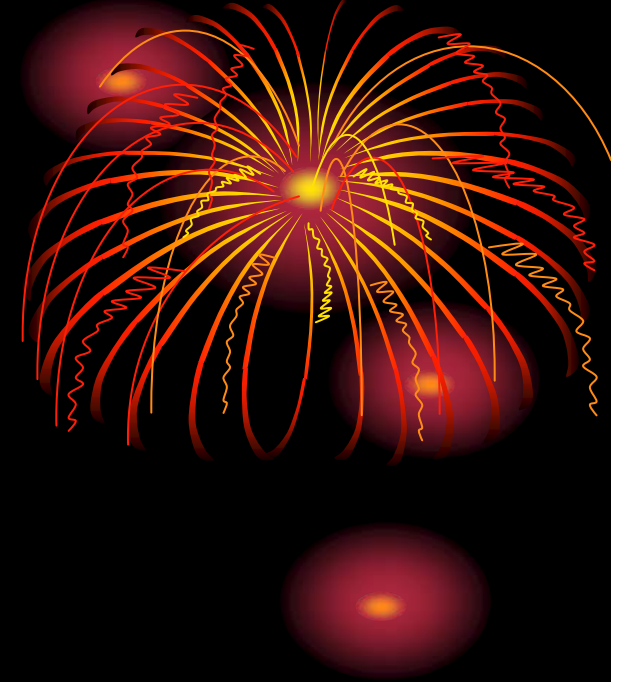


## ❖ EVERYTHING AVAILABLE PRIOR TO STUDY INITIATION

- \* DRUG
- \* IVRS
- \* LAB KITS
- \* PROTOCOLS
- \* CONSENT FORMS
- \* QOL
- \* ECG MACHINE
- \* CRF
- \* SITE AND PHARMACY FILES
- \* RADIOLOGY SUPPLIES



# QUERIES



- ❖ **IDENTIFICATION OF UNNECESSARY QUERIES**
- ❖ **GOOD CRF TRAINING**
- ❖ **SOURCE QUERIES NOT PUT INTO eCRF**
- ❖ **ASSISTANCE WITH DATA MANAGEMENT QUERIES**
- ❖ **GOOD KNOWLEDGE OF STUDY DISEASE AND PROTOCOL**



# TEAMWORK



- ❖ **WE ARE ALL ON THE SAME TEAM**
- ❖ **WORK TOGETHER TO CREATE A WIN-WIN ENVIRONMENT**
- ❖ **GOOD COMMUNICATION WITH ALL PARTIES INVOLVED**

