

## Data Quality Monitoring; What is Important?

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# Data Quality Monitoring Practical Perspectives



- Principals
- Errors of Importance
- Building Data Quality into Trials; Design to Completion

# Data Quality Monitoring

## What Does It Mean?

“Any procedure, method, philosophy that is aimed at maintaining or improving the reliability or validity of the data and the associated procedures used to generate them”

**C. Meinert**

# Data Quality Monitoring Principles

- Patient Safety
- Trial Validity and Data Integrity

# Data Quality Monitoring Principals



- Purpose is NOT to ensure that the data are 100% error - free
- Data are free of critical errors that can impact accurate and reliable results....
  - Observed treatment effects are REAL
  - Estimated magnitude is UNBIASED

# Data Quality Monitoring Errors Of Importance



*“To Err is Human”*

- Administrative Errors
- Random Errors\*
- Systematic/Non-Random\* Errors

**\*With respect to TX assignment**

# Data Quality Monitoring

## Types of Errors

- Design
- Procedural
- Data Recording
  - Random (transcription; measurement)
  - Non-random (all on one TX group)
  - Fraud (fabrication)

# Data Quality Monitoring Building into Trials

- Study Design and Protocol Development
- Data Collection
- Follow-up
- Study Close-Out

# Data Quality Monitoring Design and Protocol

- Sensible/Knowledgeable Protocol Writing Team;
  - Statistician
  - Methodologists
  - Clinical
  - Project Management
- Design + SS + Event/Definition + Measurement Tools + Follow-up + Operational Methods = Answer the Question
- Study Methods/Operations Established (SOP) and Reviewed Early

# Data Quality Monitoring Design – Error Impact

- Unclear Event Definitions; Create confusion and lead to reporting errors

*(What do you mean by Non-CNS Systemic Embolism?)*

- Unclear Follow-up Specifications; all randomized patients must be followed!

# Data Quality Monitoring CRF Development



- Sensible CRF development team;
  - Statistician
  - Methodologists
  - Clinical/Physician Investigator
  - Project/Data Management
- Aim to decrease volume and increase precision in critical data capture; Data Points + Reporting Times
- Do your CRFs really reflect the Protocol?

# CRF Issues - Example

## CRF vs Protocol Definition of Major Bleeding

### 3. Criteria for major bleeds (must be YES to at least one)

No	Yes						
<input checked="" type="checkbox"/>	<input type="checkbox"/>	a. Bleeding associated with a drop in Haemoglobin =>20 g/L	→	If yes, specify total drop	<input type="text"/>	<input type="text"/> g/dL	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	b. Required transfusion of blood of ≥ 2 units whole blood or packed red blood cells	→	If yes, specify total units	<input type="text"/>	<input type="text"/> g/L	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	c. Symptomatic bleeding in a critical area or organ. <b>Mark [x] all that apply:</b>					
		<input type="checkbox"/> i. Intraocular		<input type="checkbox"/> ii. Intraspinal	<input type="checkbox"/> iii. Intramuscular	<input type="checkbox"/> iv. Retroperitoneal	
		<input type="checkbox"/> v. Intra-articular		<input type="checkbox"/> vi. Pericardial	<input checked="" type="checkbox"/> vii. Gastrointestinal		
		<input type="checkbox"/> viii. Other					
		<i>Specify</i>					
<input checked="" type="checkbox"/>	<input type="checkbox"/>	d. Symptomatic Intracranial	→	If yes	<input type="checkbox"/> Subdural	Report # <input type="text"/>	
					<input type="checkbox"/> Intracerebral		
						<i>Complete STROKE REPORT CRF 110</i>	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	e. Associated with hypotension requiring use of intravenous inotropic agents					
<input checked="" type="checkbox"/>	<input type="checkbox"/>	f. Required surgical intervention to stop bleeding	→	If yes, what procedure	<i>Specify</i>		
<input checked="" type="checkbox"/>	<input type="checkbox"/>	g. Death	→	<i>Complete DEATH REPORT CRF 126</i>			

# CRF Issues - Example

## Limitations of Reporting when data grouped

No Yes Other vasodilator

**PART C. BETA BLOCKERS, CALCIUM CHANNEL BLOCKERS AND DRUGS USED IN AF** *(If yes, specify below)*

	Baseline	No Change	Started	Stopped		Baseline	No Change	Started	Stopped
1. Calcium channel blockers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Amiodarone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/> Verapamil or diltiazem					5. Other antiarrhythmic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Other									
2. Beta blocker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
3. Digoxin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					

# Data Quality Monitoring

## Building a Data Base



- Data Base Design Consistent With Protocol and CRFs; EDC and Faxed
- Edit/Consistency and Logic/Range Checks
- Query Reports
- Operator Training/Validation/Error Estimation

# Sophisticated Strategies!



**“This will be our user error tracking center. Joanne will see every user error as it occurs, and then yell the solution toward the proper cubicle.”**

# Data Quality Monitoring Follow-up - Planning/People



- Sensible Plan for Evaluating the Data; Focus and Risk Based to Minimize Potential Bias
- Standard Documents and Instructions (Manuals etc.)
- Quality Coaches and Trial Oversight
  - *Operations/Project Management Team*
  - *Steering Committee*
  - *DSMC*
  - *Adjudication*
  - *Data Management Team; Central Data Monitoring*
  - *Site Monitoring Teams (only where necessary!!)*

# Data Quality Monitoring Follow-up: Areas of Importance



- Randomization/Recruitment
- Expected Study Procedures and Reporting
- Data Recording
- Data Entry/Processing

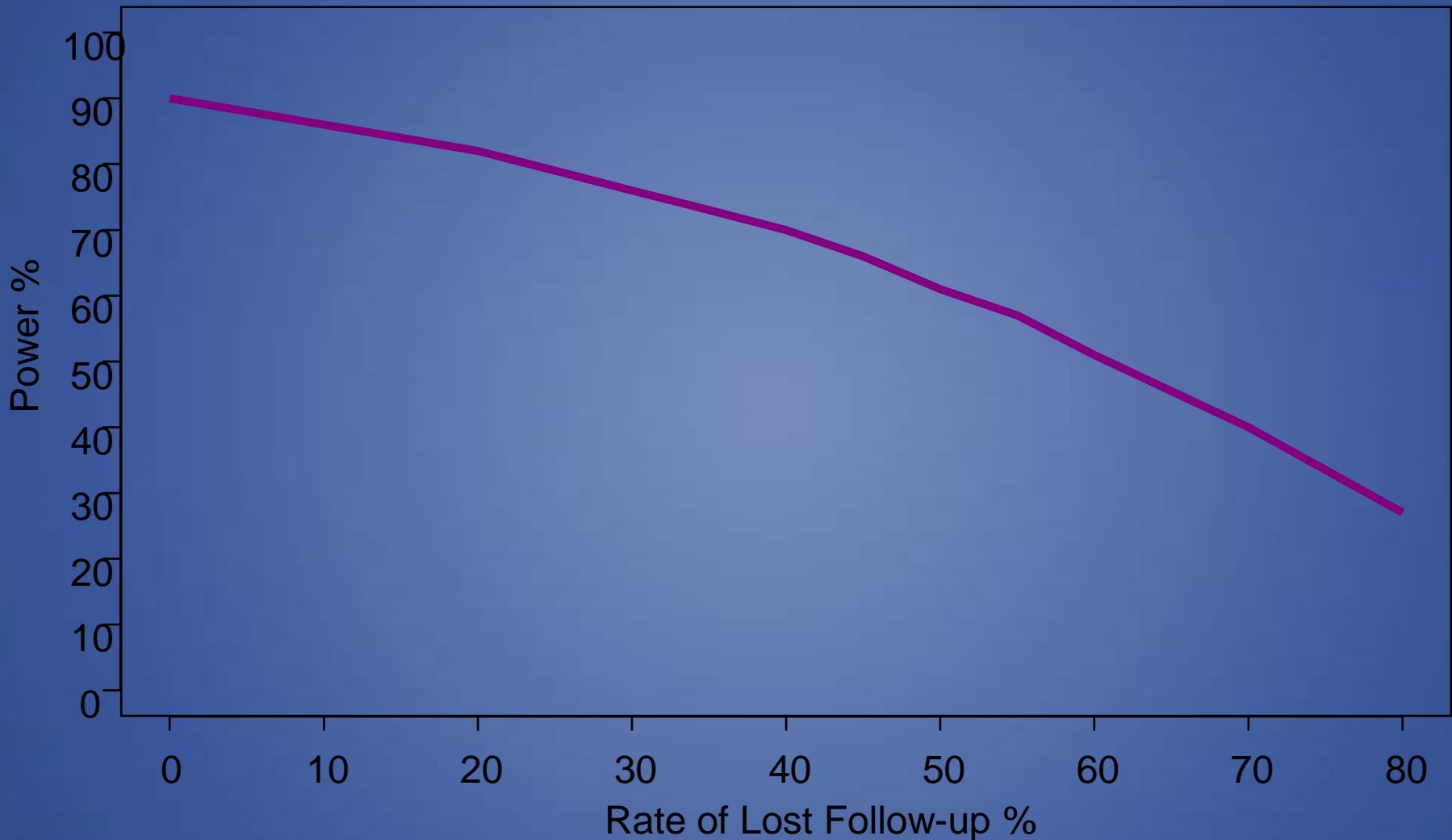
# Data Quality Monitoring Follow-up: How

- Ongoing Central Monitoring through the data..
  - Recruitment/Randomization Patterns or Irregularities
  - Timeliness of Critical Data Flow
  - Data Collected and Reported Procedures (rates etc.)
  - Adherence to Follow-up Schedule
  - Reporting of Events
  - Data Surveillance Programs (Implausible Values, unusual reporting patterns)

# Data Quality Monitoring Follow-up: Close Out

- Early Planning with Study Leaders and Collaboration With Sites
- Data Disposition and Critical Focus
- Strategies for Complete Follow-up on ALL Patients
- Adjudication and Event Processing

# Data Quality Monitoring LTFUP and Impact on Power



# Data Quality Monitoring



**NO STUDY IS BETTER THAN THE QUALITY  
OF ITS CRITICAL DATA!**

# Investigator Key Messages



- Sensible Planning of your Protocol!
- Identify risks to potential biases early and develop sensible strategies! Build into all phases
- Effective Foundation for Trial Oversight (Study and Data)
- Partner with Your Data! Be an active Quality Coach
  - Review early to detect trends and errors
  - Review regularly as data accumulates and changes
- Meet Regularly with Study Leaders/Team to detect issues early!