

Fraud and Misconduct



Module 7 Topic 7

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- Horror Stories in Scientific Research do not always start and end with Fraud but includes mishaps and misconducts at the level of the Sponsor, Investigators and IRB/IEC

Clinical Quest



Fraud Associated Characters

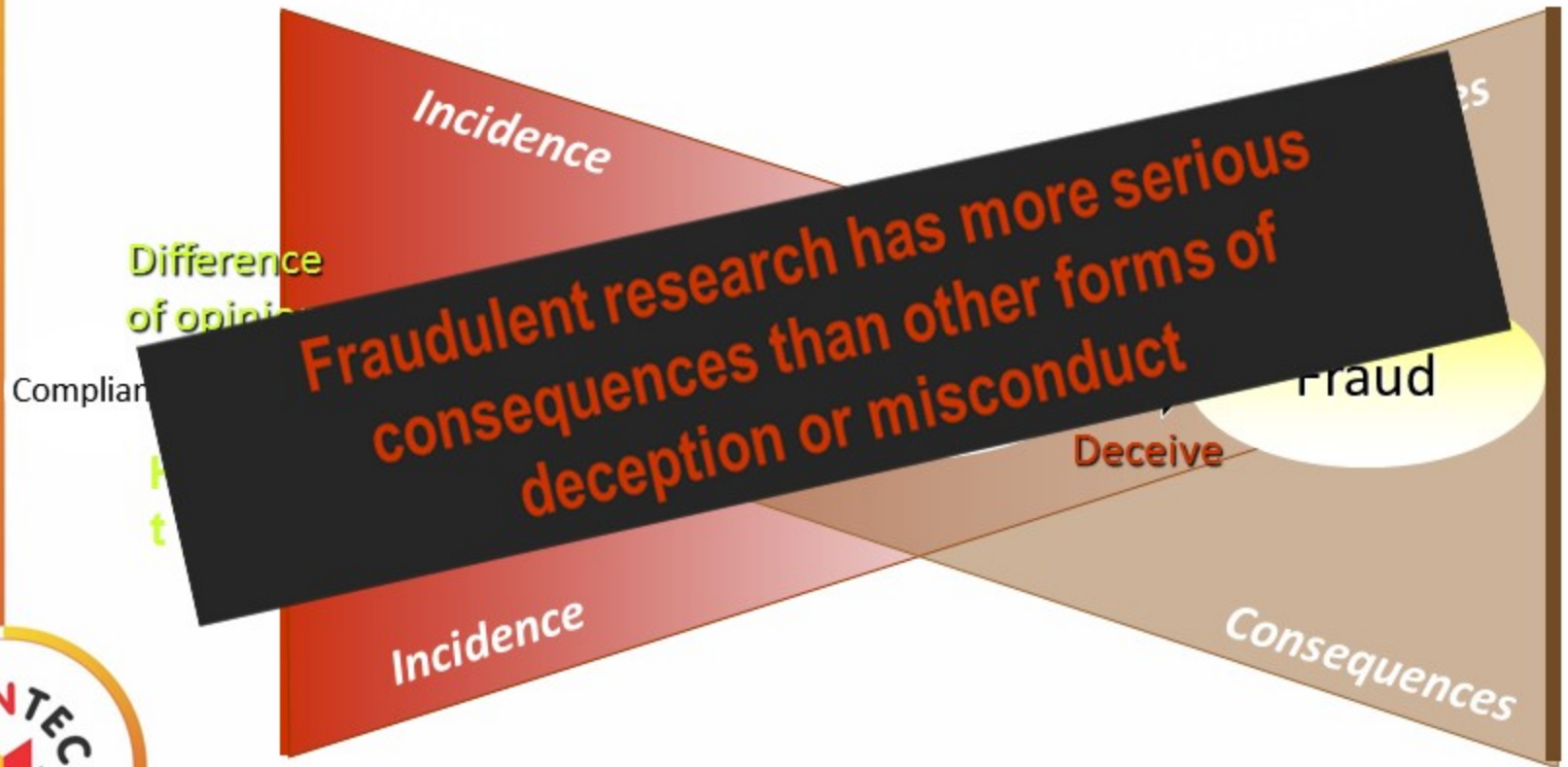
Incompetence	Bad Science
Arrogance	Poor Ethics
Greed	Contempt for Patients
Ambition	Contempt for Rules
Laziness	Contempt for sponsor
Dishonesty	Poor team spirit



Compliance In Clinical Trials



The Non Compliance Continuum



THE NON COMPLIANCE CONTINUUM



Drivers Of Non Compliance

**Honest
Error**

- Failure to see the “experiment”
- Complicated study procedures
- Poor infrastructure
- Miscalculation/misjudgment

Compliance



Noncompliance

**Difference of
opinion**

- Study protocol ambiguous
- Rationale of study unclear
- Patient inconvenience
- Overrated techniques/ equip.



Misconduct

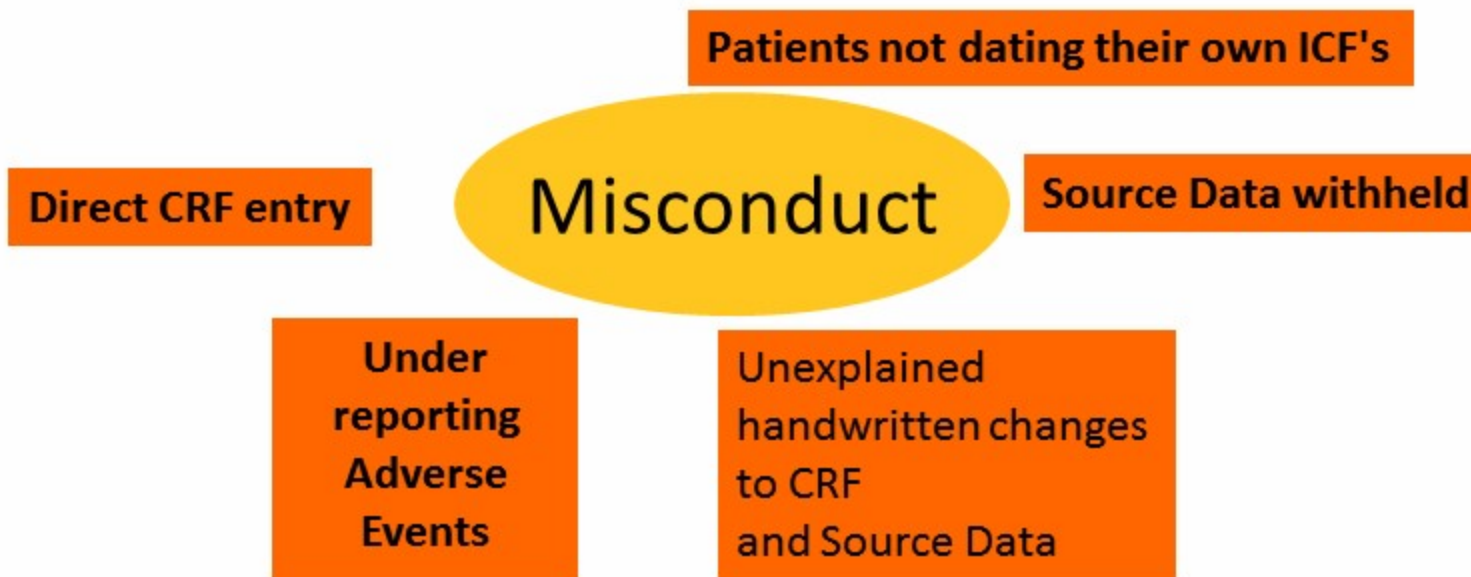
Pre-conceived notions



Major Drivers Of Misconduct



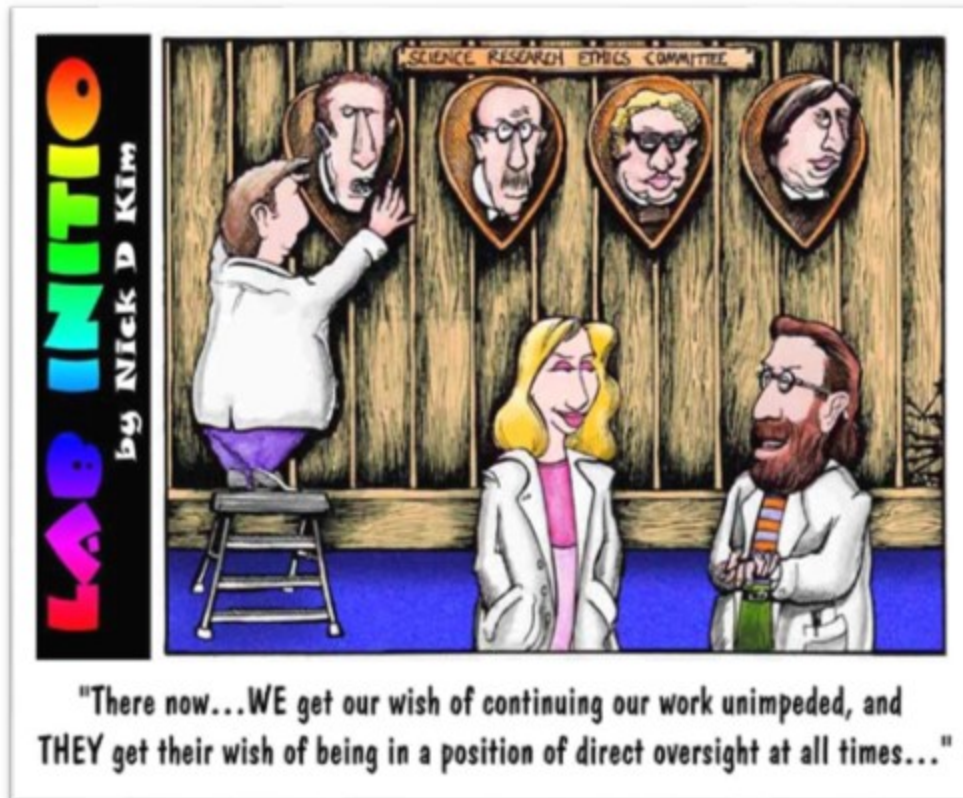
Examples Of Scientific Misconduct



Fraud

“Scientists aren’t saints. The field is so competitive that many misbehave in many ways; few falsify results.”

-David Goodstein



Drivers Of Fraud

Misconduct

Fraud

"The most difficult crime to track is the one which is purposeless"
- Sherlock Holmes



Incidence of Fraud

Believed to be uncommon

- Estimated to be 4-5% annually
- No systematic registration (except UK, Denmark & USA)



“We believe probabilities and choose the most likely.
This is very scientific use of imagination”

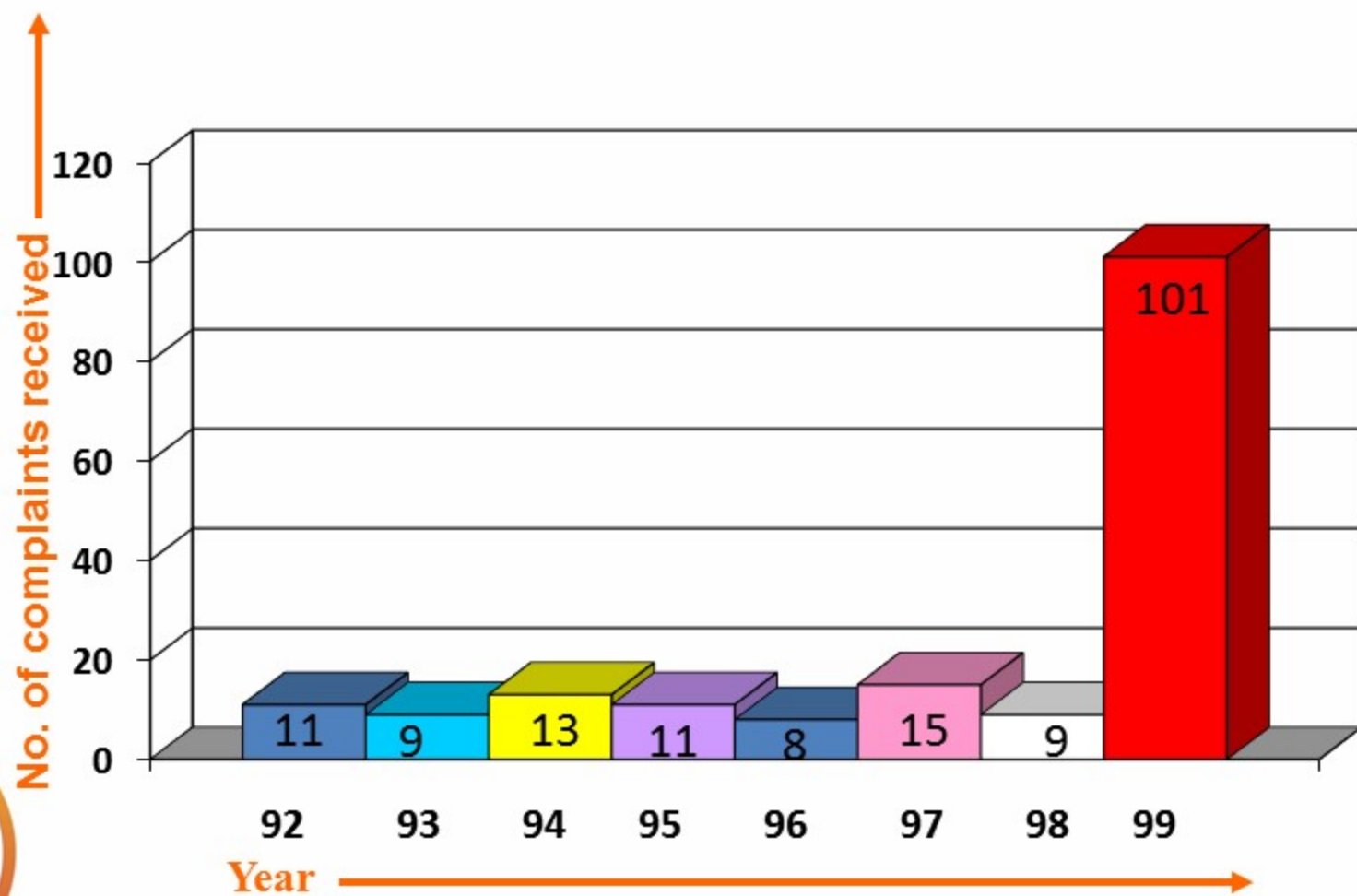
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"I am going to enter you as three patients, in your name, nee name and pseudonym."



Complaints Lodged at the US FDA



The incidence of reporting fraud is on the increase



Falsification of Data

- Falsification of data includes:
 - creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred



Examples of falsification of data include but are not limited to

- Creating data that were never obtained;
- Altering data that were obtained by substituting different data;
- Recording or obtaining data from a specimen, sample or test whose origin is not accurately described or in a way that does not accurately reflect the data
- Omitting data that were obtained and ordinarily would be recorded



Examples of Fraud

- Tampering with eligibility criteria for inclusion/continuation
- Pt. disguised & entered several times
- Pts. enrolled in other concurrent studies
- Investigator enrolling himself in study



Examples of Fraud (contd)

- Forged Consent Forms
- Falsifying EC approval
- Fabricating lab results
- Charging for test article
- Plagiarizing Publications

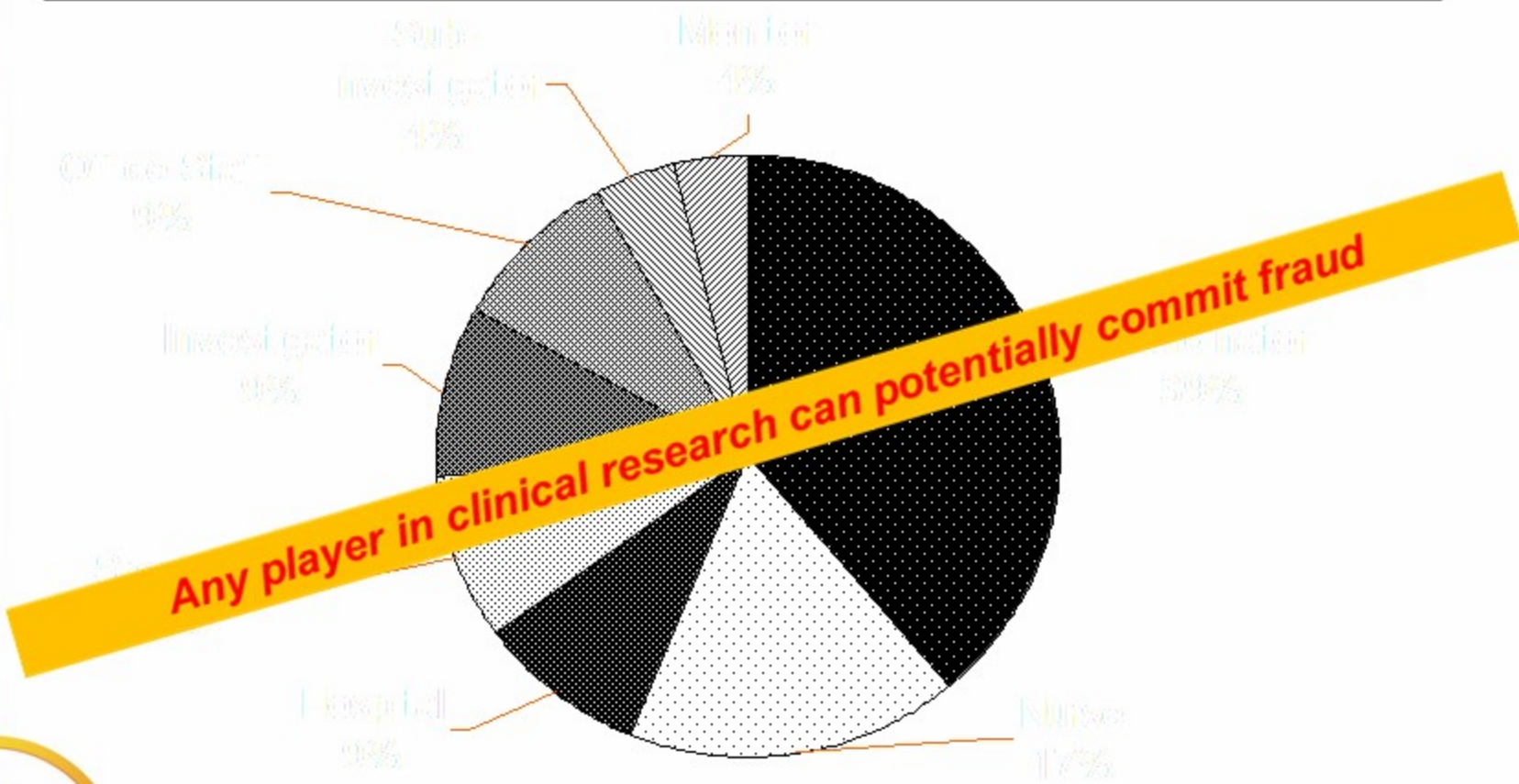


“As to the (forged) signatures of 4 out of 80 patients...we are talking of a margin of error of 5%- this is within recognized statistical limits.”

- Dr. Robert Fiddes



The Blame Game - Who Gets The Blame?



Impact of Fraud

- Patient abuse & exploitation
- Integrity of submitted/published data – questionable
- Rejection of data/ reanalysis without suspect data
- Licenses issued based on unreliable data - Public health endangered
- Waste of public finances



Management Strategies

Prevention

- Identify and eliminate/
minimize risk factors

Detection

- Monitor and recognize signs

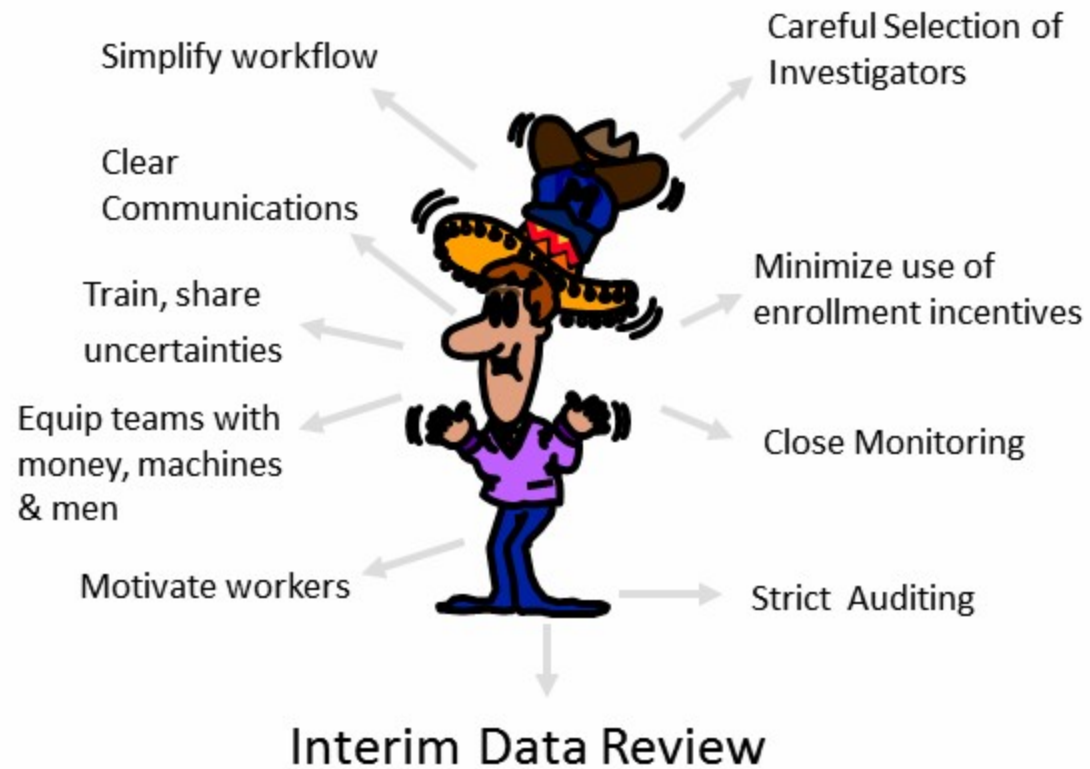
Correction

- Promptly investigate and
report findings



One should be able to Prevent, Recognize and Report

Preventive Modalities



Gathering Proof

- Remain discreet – do not accuse!
- Look for:
 - Perfect documentation
 - Patterns across patients
 - Spurious data
 - Tampering of documents
 - Deviation from other centers
 - Suspicious behavior



“There is nothing like first-hand evidence”



Detection Tools

- Get Technical- Read ECGs, lab results, don't just inventory
- Fill in the Blanks - Question missing dates & time
- Don't be intimidated - tell the emperor he has no clothes
- Don't shoot the messenger - believe the monitor, put the burden of proof on the person suspected
- Beware of blame shifting
- Cultivate whistleblowers - establish rapport with study staff, be approachable and available, listen to grievances

“There is nothing more deceptive than an obvious fact”



The Art of Detection

“When you have eliminated
all of which is impossible,
then whatever remains,
however improbable, must
be the truth”

- Sherlock Holmes



When First Detected

- Do not suppress suspicions
- Handle discretely
- Do not reveal suspicions at site
- Do not immediately start using terms such as “fraud”
- Seek advice and help
- Confirm suspicions with objective evidence
- Collect circumstantial evidence and data



Action against Misconduct

- Warning letter to investigator; demand improvement
- Increasing monitoring activity and training
- Act to save data at the site – where feasible
 - **Correct the documentation**
 - **Reconsent all patients**
 - **Validate all data → modify the database**
- Justify exclusion of data from final report
- Worst case : close centre and avoid using again



Principal steps on detecting misconduct: saving the data
and ensuring patient safety

Responding to Fraud

- Vital to have a company SOP to follow
- Initiated by suspicion by any member of staff
- Suspicion reported to line manager
- Suspicion relayed to operational manager and/or QA



Responding to Fraud (contd)

- Evidence reviewed to substantiate or remove suspicion
- If substantiated, promptly notify senior management (& sponsor)
- Undertake for cause audit and statistical data review/ analysis
- If confirmed, determine course of action as per SOP



Data probably compromised beyond recovery

Action against Fraud

- Close errant centre and prevent future use
- Inform the relevant regulatory agency
- Inform the errant investigator's institution/ professional body
- Inform the Ethics Committee



Understand that fraud cannot be fully eliminated and
work towards minimizing it

