



Data Integrity: A QA Perspective



What is Quality?

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- Fit for use
- Free from defects
- Meets a certain predetermined quality standard



What is Quality Assurance? Colorado State University

Series of activities designed to **assure** [someone] that the product is 'fit for purpose' and intended quality standards have been met.

[Managers, researchers, regulators,
sponsors/clients, technicians, QC, consumers]



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Quality Assurance Professional

Colorado State University





Research Integrity & Compliance Review

Local Discovery Global Impact

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[RICRO Quality Program](#)

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[Regulatory Affairs Services](#)
[RQP Advisory Board](#)
[Regulatory Readiness Program](#)

Quality Links

[Good Clinical Practices \(GCP\)](#)
[Good Clinical Laboratory Practices \(GCLP\)](#)
[Good Documentation Practices \(GDP\)](#)
[Good Laboratory Practices \(GLP\)](#)
[Good Manufacturing Practices \(GMP\)](#)
[Good Scientific Practices \(GSP\)](#)
[Method Validation](#)
[ClinicalTrials.gov](#)
[IND/INAD Permitting](#)
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Examples & Templates

[Protocols](#)
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[SOP's](#)
[Forms](#)

Contact Quality Program

RICRO Quality Program

Quality Policy

At CSU we are committed to the quality of our research efforts and endeavor to meet appropriate good quality system requirements as appropriate in all our research, clinical and manufacturing efforts

Quality Program

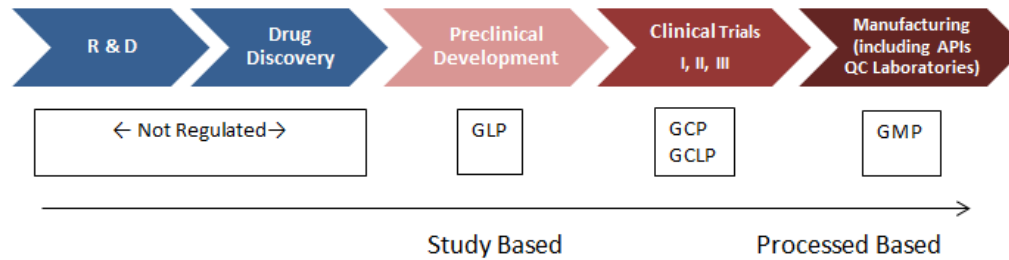
The CSU Quality Program provides assistance to researchers in meeting federally-mandated or sponsor-specified quality standards by supporting the development and maintenance of laboratory-specific quality systems, programs, education and training. The CSU Quality Program provides institutional oversight through Quality Assurance inspections and monitoring services.

The goals of these standards are to provide reliable, high quality research data or products for the federal agencies, CSU Sponsors and the public.

Generally these standards have become known as the 'GXP's' or individually as:

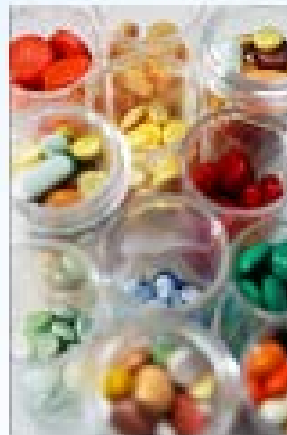
- **GCP** [Good Clinical Practices](#)
- **GCLP** [Good Clinical Laboratory Practices](#)
- **GDP** [Good Documentation Practices](#)
- **GLP** [Good Laboratory Practices](#)
- **GMP** [Good Manufacturing Practices](#)

Although most research these days has some aspect of regulatory governance and oversight, research quality standards become mandatory by law when the results of CSU activities affect public health by establishing the safety of products regulated by federal agencies, such as foods, cosmetics, drugs, pesticides, toxic substances, etc. In order to protect and assist researchers who are conducting or are planning on conducting regulated studies or activities, the

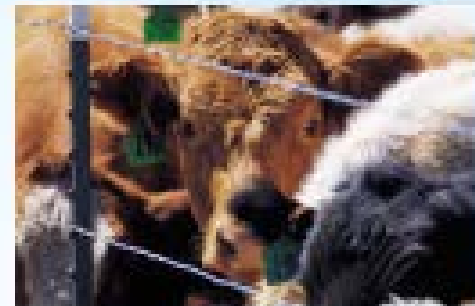


Human and Animal Drugs

Food and drug additives



Animal food additives



Biologics



Pesticides



Medical devices and electronic products



- Increase quality, integrity and reliability of data
- Increase confidence that data are of known, documented quality
- Access to funding otherwise not available without meeting a known quality standards
- Support Industry needs and regulatory requirements
- Support 'bench-top to market' research and manufacturing activities



Any information that is necessary for the reconstruction and evaluation of the research activities or processes.

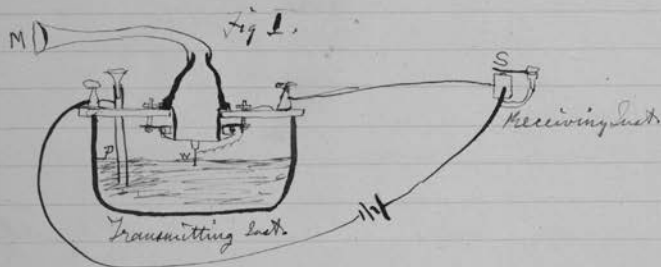
How do you know?

- *Who, What, Where, When, How*



40

March 10th 1876



1. The improved instrument shown in Fig. I. was constructed this morning and tried this evening. P is a brass pipe and W the platinum wire M the mouth piece and S the armature of the Receiving Instrument.

Mr. Watson was stationed in one room with the Receiving Instrument. He pressed one ear closely against S and closed his other ear with his hand. The Transmitting Instrument was placed in another room and the doors of both rooms were closed.

I then shouted into M the following sentence: "Mr. Watson - Come here - I want to

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see you". To my delight he came and declared that he had heard and understood what I said.

I asked him to repeat the words - ~~He said~~ He answered "You said 'Mr. Watson - come here - I want to see you'." We then changed places and I listened at S while Mr. Watson read a few passages from a book into the mouth piece M. It was certainly the case that articulate sounds proceeded from S. The effect was loud but indistinct and muffled.

If I had read beforehand the passage given by Mr. Watson I should have recognized every word. As it was I could not make out the sense - but on occasional word here and there ~~was~~ quite distinct. I made out "to" and "out" and "further"; and finally the sentence "Mr. Bell do you understand what I say? Do-you-understand-what-I-say" came quite clearly and intelligibly. No sound was audible when the armature S was removed.



WHALE SHARK STUDY DATA COLLECTION FORM

Support Vessel: _____

Captain: _____

Country/Island: _____

Date: _____ Time: _____

SURFACE DATA

Air temperature: _____

Cloud conditions: _____

Wind direction & strength: _____

Barometric Pressure: _____

GPS: _____

Location (Describe surroundings - on surface, on bottom, etc.)

Size of shark: _____ Sex of shark: _____

Notes: (Describe scars & markings. Mark any unusual pattern or scars on the drawing below. Attach photo if available.)

SUBSURFACE DATA

Visibility: _____ ft.
(measured or estimated)

Water Temperature
Bottom: _____ Surface: _____

Chemistry: _____

Current

Direction: _____ to _____

Strength: _____

Waves

Height: _____ Strength: _____

Water depth: _____

Depth shark encountered: _____

Swimming direction: _____

Environmental conditions: (reef,
plankton, schooling fish)



TAGGING INFORMATION

Visual ID Tag # _____ Tagger: _____ Date: _____

Satellite Tag # _____ Tagger: _____ Date: _____

Tissue Sample# _____ Vial # _____ Date: _____

Name of shark: _____

PHOTO/VIDEO

U/W Photos by: _____

U/W Video by: _____

REPORT COMPLETED BREPORT
COMPLETED BY: _____

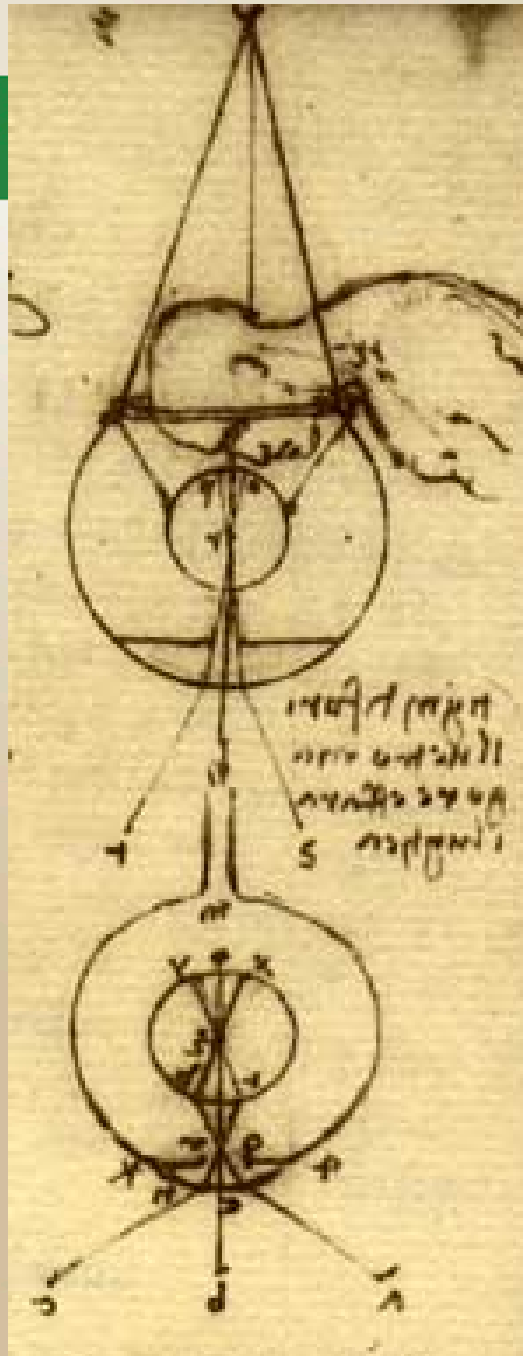
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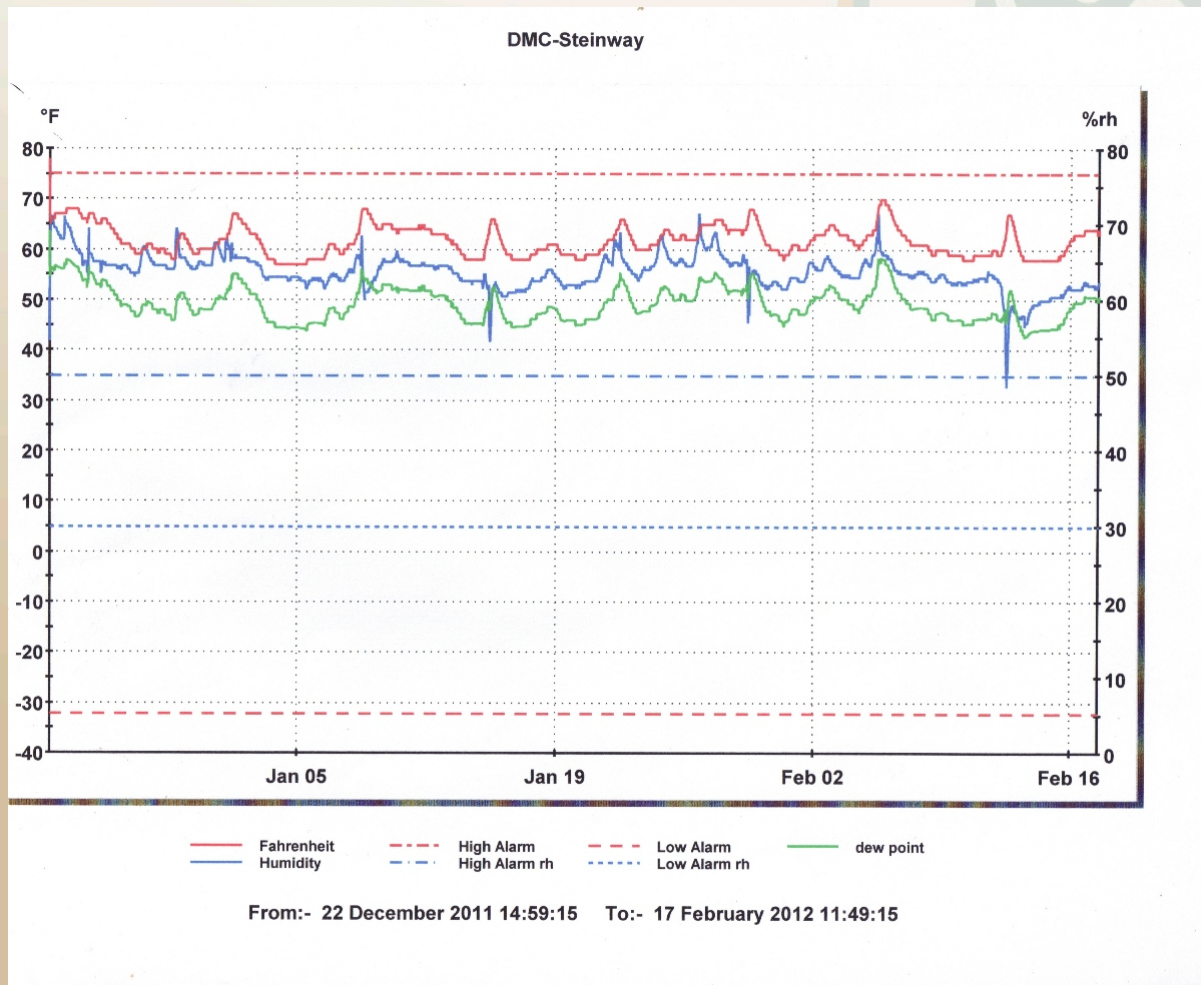
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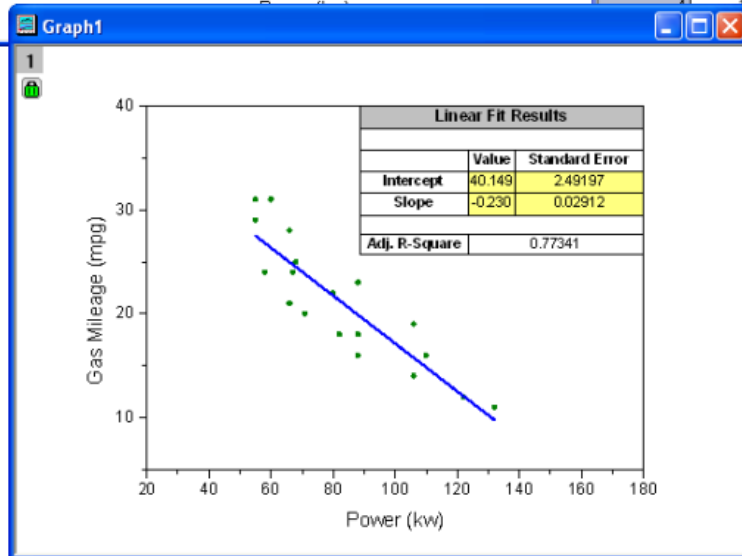
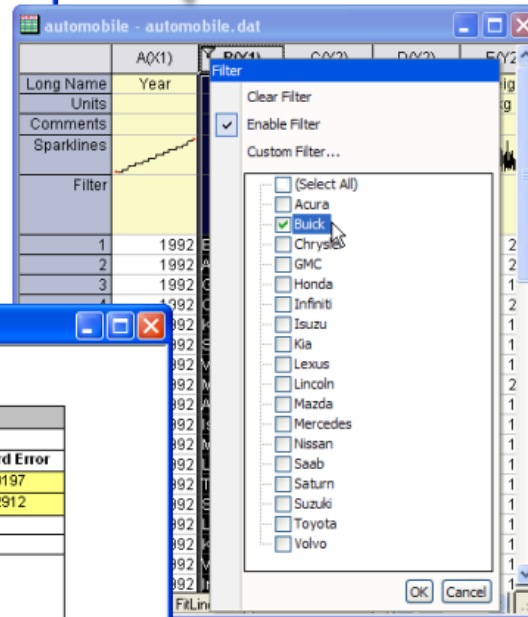
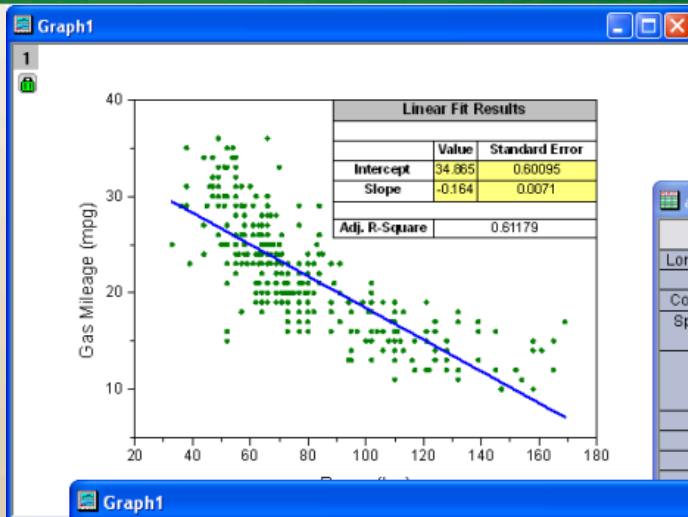
BEHAVIOR OF THE SHARK

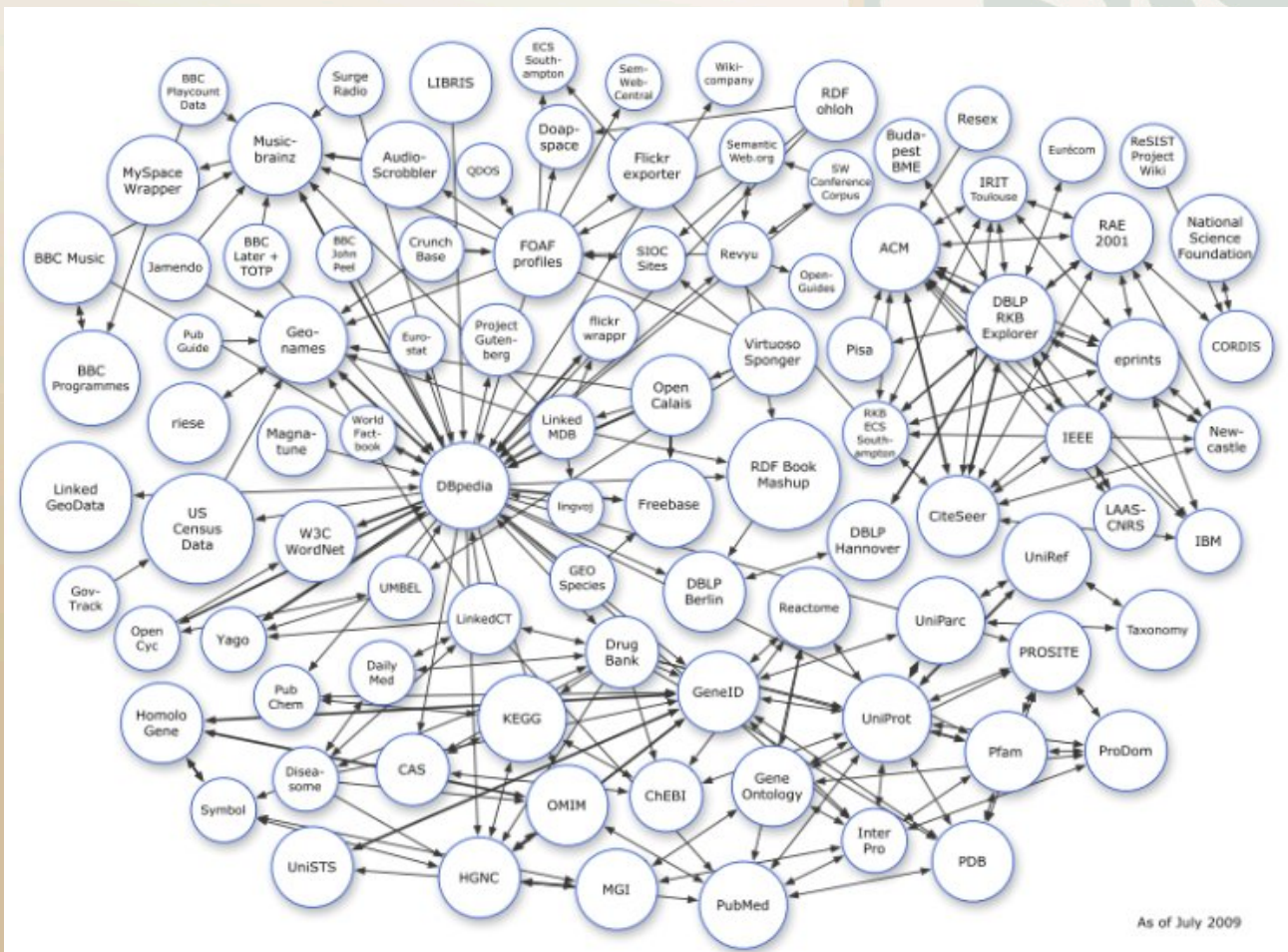
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Data Integrity?

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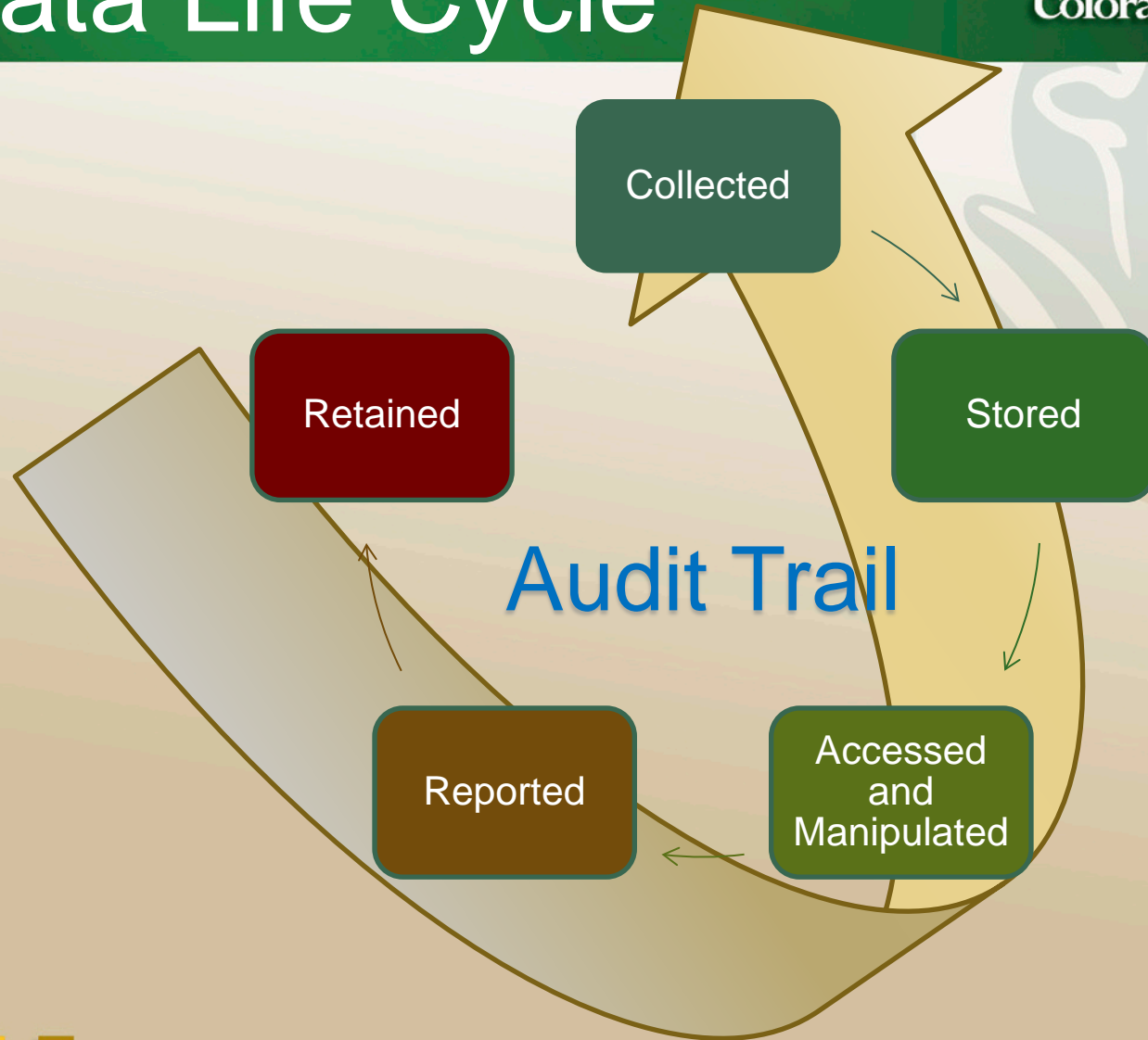
- **Data integrity** refers to maintaining and assuring the accuracy and consistency of data over its entire life cycle
- Data integrity is the opposite of data corruption, which is a form of data loss

Wikipedia, 28April2015



Data Life Cycle

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What is your Data Quality System? Colorado State University

- Research Plan/Protocol
- Procedures/Policies
- Training
- Monitoring/Mentoring
- Reporting
- Data Retention/Archiving

❖ Is there a Quality Culture? Is it known? Is it documented?



Say what you do!
Do what you say!
Prove it!
Improve it!



Write it down!

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**If it isn't
written, it
didn't happen!**



50 mg/ml



Source Data Integrity

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ALCOA

Attributable

Legible

Contemporaneous

Original

Accurate

CCC

Credible

Consistent

Corroborated

GOOD DATA PRACTICES

ALCOA

Attributable – Dated signature of those involved

Legible – Understandable, in permanent ink

Contemporaneous – Recorded as generated

Original – First time recorded, appropriately

Accurate – Correct and Complete with units, etc.

CCC

Credible

Consistent

Corroborated

DATA CORRECTION PROCEDURES

1. Single line through original data to be changes, do not obscure original
2. Place correct data so clearly understood
3. Give reason for change
4. Sign and date

Example:

~~3.234~~ 3.355

CMB 2/24/2013 *wrong animal weight*

Physical Integrity

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Logical integrity

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Data Manipulation

Insert Link

Insert Image

Sort table by column in order

Selected rows:

Combine cells in a row:

Selected columns:

Combine cells in a column:

Selected rows:

Add row(s)

Selected columns:

Add column(s)

Swap rows and

Move row row

Swap columns and

Move column column



Logical integrity

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	A	B	C	D
1	29,65112			
2	34,3431			
3	35,54305			
4	34,58406			
5	30,43157			
6	20,94134			
7	40,43592			
8	34,1622			
9	38,28489			
10	42,74505			
11	37,1119			
12	37,86487			
13	37,80752			
14	36,332			
15	30,7895			

Microsoft Excel - Newton

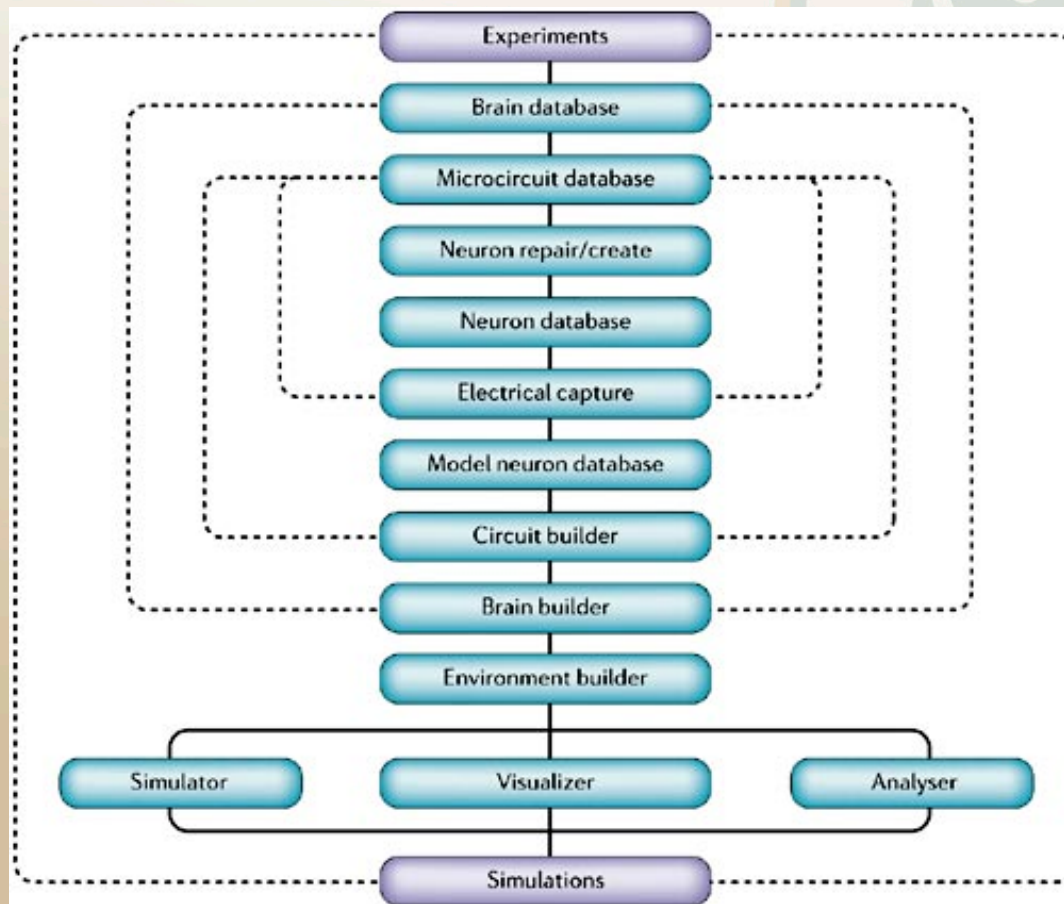
File Edit View Insert Format Tools Data Window Help

LINEST \times \checkmark = $=\$D\$1+EXP(\$D\$50)*EXP(\$C\$50*A5)$

	B	C	D	E	F	G
1	Ambient Temp (°C)=		18.9			
2						
3	Model	Temperature (°C)	ln(T Temp)	Linear Regression	Cooling Data	Derivative (T')
4						
5	65.24	65.24	$=\$D\$1+EXP(\$D\$50)*EXP(\$C\$50*A5)$			
6	63.39	62.65	3.78			
7	61.61	60.04	3.72			
8	59.90	57.89	3.66			
9	58.26	55.54	3.60			
10	56.68	53.58	3.55			
11	55.17	51.98	3.50			
12	53.72	50.43	3.45			
13	52.33	49.06	3.41			
14	50.99	47.45	3.35			
15	49.71	46.15	3.31			
16	48.48	45.12	3.27			
17	47.29	44.11	3.23			
18	46.16	43.11	3.19			
19	45.07	41.89	3.14			
20	44.02	41.04	3.10			
21	43.02	40.20	3.06			
22	42.05	39.42	3.03			

Weak Links?

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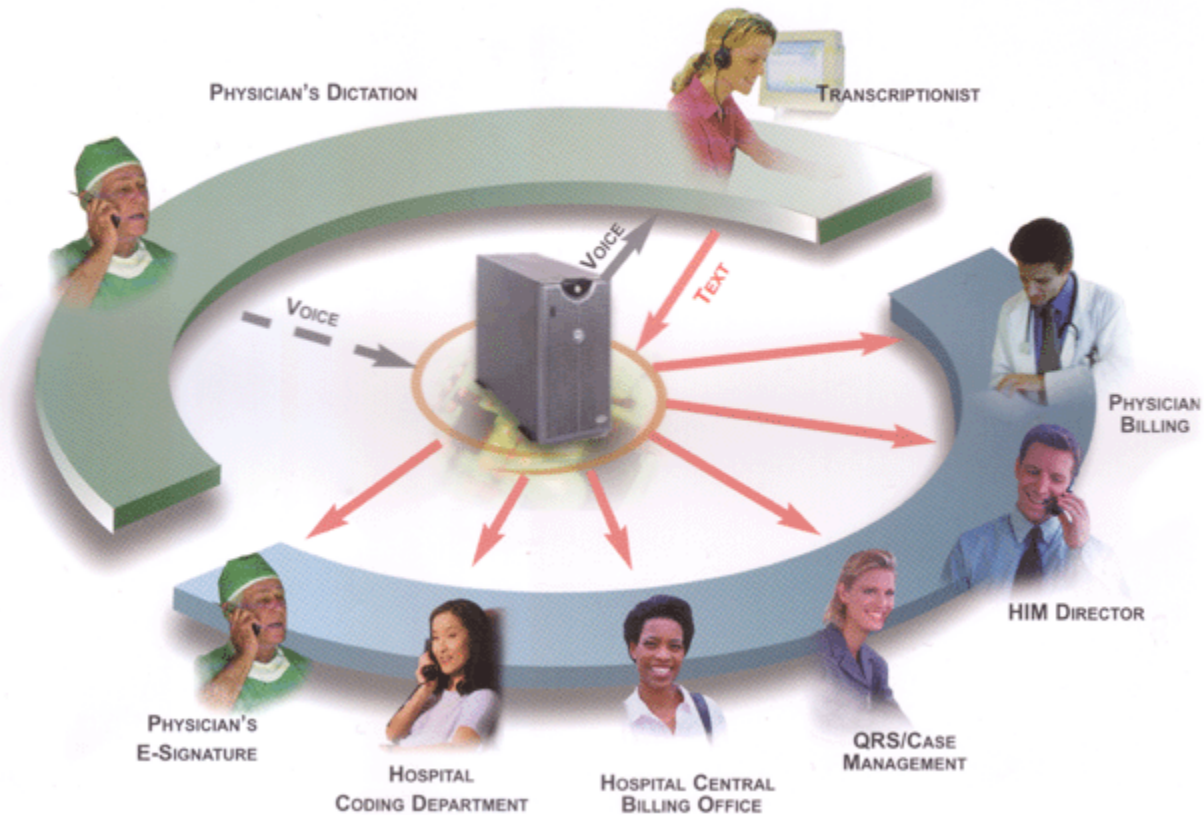


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Logical integrity

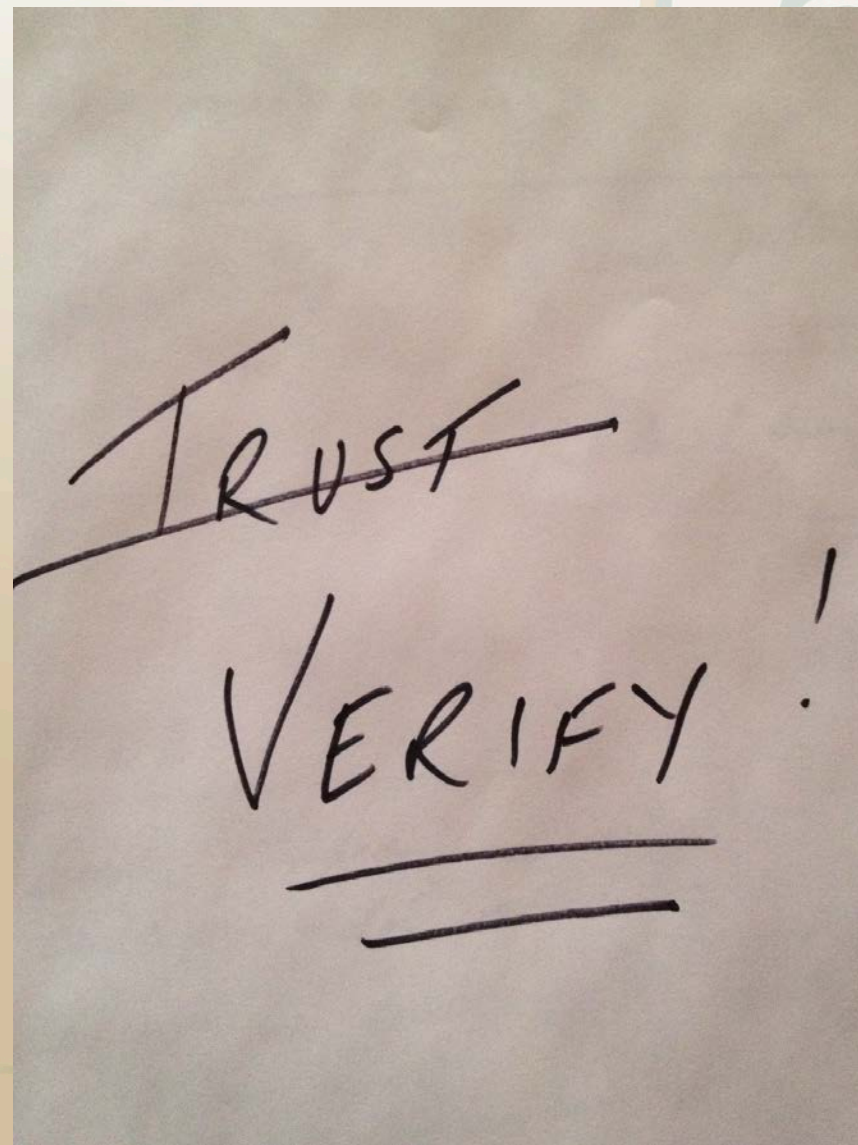
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Back Office Automation With Med-Scribe



Overall data integrity policy

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Challenges

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- What is your **source data**?
- What are the **quality expectations** of your source data?
- What **system** do you have to communicate and ensure data quality and integrity throughout the data cycle?
- How do you **measure and trend** your data integrity? How do you know?

