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Contemporary challenges in national and european health care systems

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# Title: Practical approaches to handling clinical and operational data

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# Contents

**1. Clinical Data Types:** Structured vs. Unstructured & RWD.

**2. Data Integrity:** ALCOA+ and FAIR Principles.

**3. GDPR in Medicine:** Consent, Vital Interest, and Anonymization.

**4. Critical Appraisal:** Spotting Bias and Misleading Visualizations in Medical Literature.

**Objectives:**

- ❑ Categorize healthcare data types (e.g., EHR, Genomic, sensor data).
- ❑ Apply ALCOA+ principles to ensure data integrity in clinical records.
- ❑ Differentiate between Pseudonymization (Key-coded) and Anonymization (Irreversible).
- ❑ Identify lawful bases for processing data in clinical care vs. research.
- ❑ Critically Assess medical statistics and visualizations for bias (e.g., Relative vs. Absolute Risk).

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# Introduction

**Data as a Diagnostic Tool: Modern healthcare is data-driven.**

**The Challenge: Managing high volumes of sensitive patient information.**

**The Goal: Responsible handling that ensures Patient Safety and Data Privacy.**

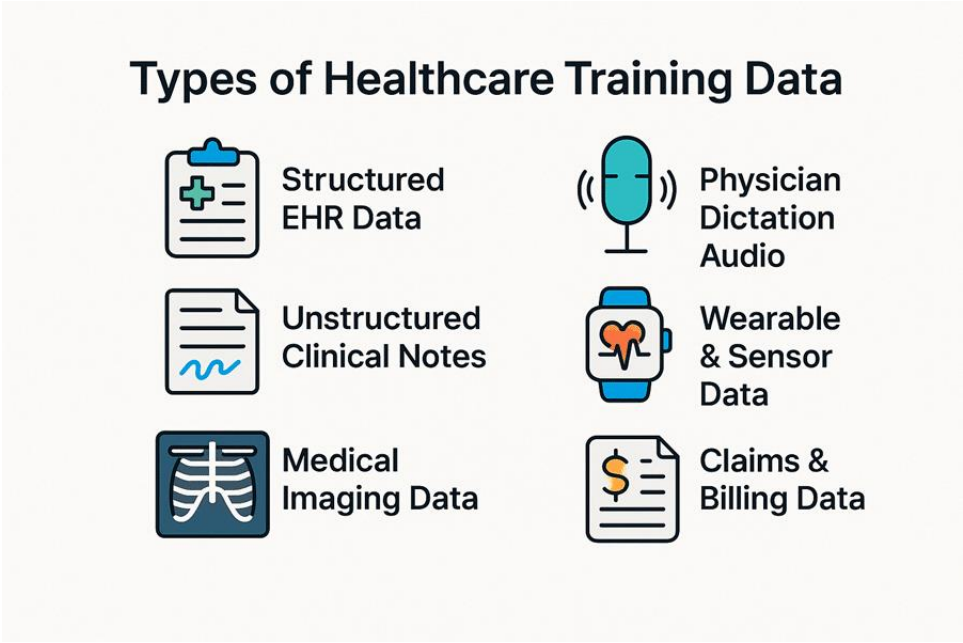
**Key Concept: "Garbage In, Garbage Out" – Poor data quality leads to clinical errors.**

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# Characteristics of Data

## Types of Data in Healthcare

1. Structured Data: Lab results, Vital signs, Coding systems (ICD-10, SNOMED, ATC codes). Machine-readable.
2. Unstructured Data: Clinical narratives, Discharge summaries, Imaging reports. Requires NLP/Human review.
3. Real-World Data (RWD): Wearables, Registries, Insurance Claims.
4. Genomic/Omic Data: High-volume, highly sensitive biological data.



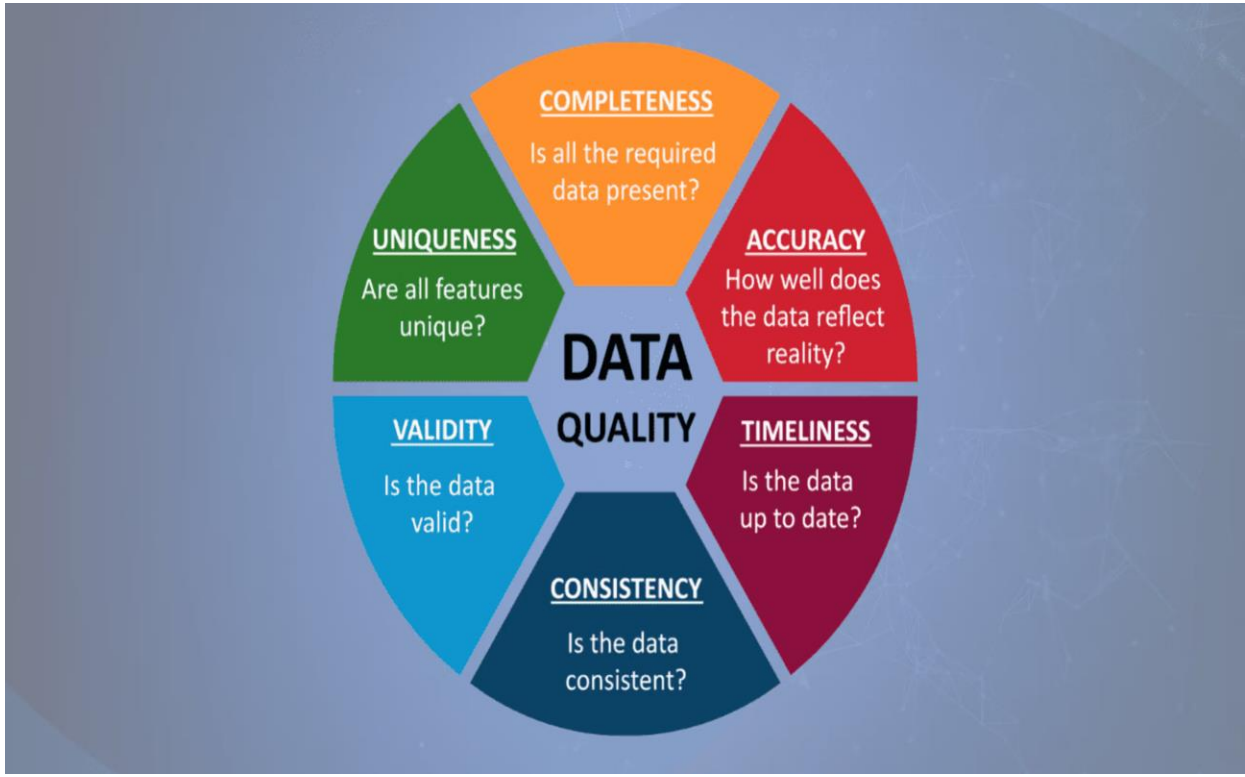

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# Data Quality: The ALCOA+ Standard

The Gold Standard for Clinical Research (GCP)

- Attributable: Who documented it?
- Legible: Can it be read?
- Contemporaneous: Recorded at the time of the event.
- Original: First record (source document).
- Accurate: Error-free.
- + Plus: Complete, Consistent, Enduring, Available




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# FAIR Principles for Scientific Data

Data Stewardship for Research
Findable: Metadata and persistent identifiers (DOIs).
Accessible: Retrievable via standard protocols.
Interoperable: Uses shared medical vocabularies (e.g., LOINC for labs).
Reusable: Clear usage licenses and provenance.




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# Fundamental Principles of Clinical Data Stewardship

What is 'Personal Data'?

Definition: Any information relating to an identified or identifiable natural person.

Direct Identifiers: Name, Social Security Number.
Indirect Identifiers: MRN, Clinical Trial ID, Rare Diagnosis + Zip Code.
Special Category Data : Health data, Genetics, Biometrics require higher protection.

## De-identification: The Clinical Distinction

1. Pseudonymization (Reversible):
- ❖ Data is separated from identifiers (Key-coded).
- ❖ Example: Clinical Trials (Subject 001).
- ❖ Legal Status: Still Personal Data under GDPR.

2.Anonymization (Irreversible):
- ❖ Impossible to re-identify the patient.
- ❖ Example: Aggregated public health stats.
- ❖ Legal Status: Not Personal Data (GDPR does not apply).

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# Data Protection Principles

- Purpose Limitation: Don't use clinical data for research without approval.

- Data Minimization: "Need to know" basis. Access only relevant records.

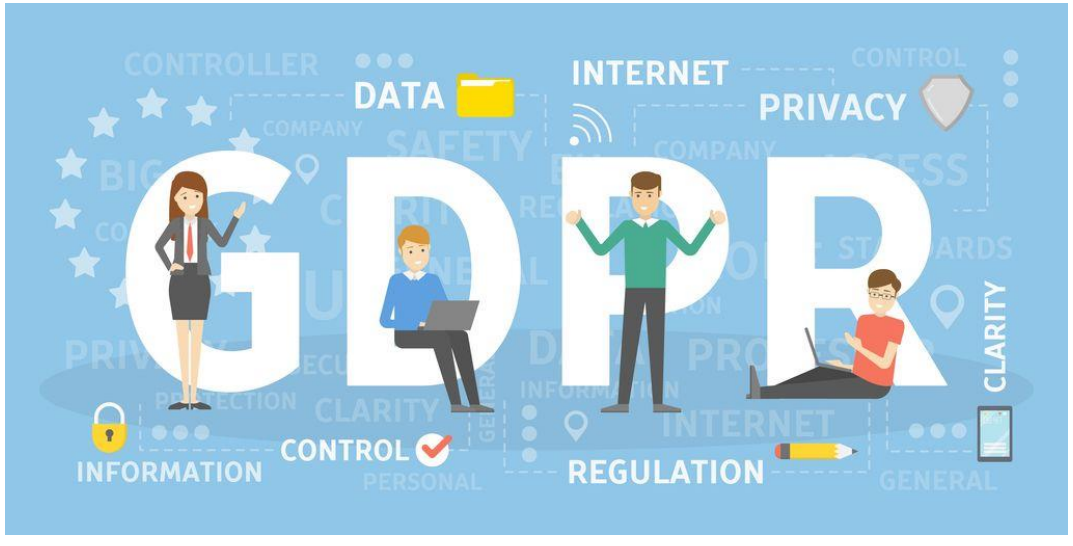
- Storage Limitation: Do not keep local copies of patient lists indefinitely.

- Integrity & Confidentiality: Protect against unauthorized access (e.g., don't share passwords).

## GDPR and Healthcare

Scope: Applies to all patient data in the EU

Clinical Impact:
-Mandates secure storage (Encryption).
-Requires reporting of data breaches (e.g., lost notes) within 72 hours.
-Ensures patients can access their own records.




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## Lawful Basis for Processing

• Informed Consent: Required for clinical trials / research.

• Vital Interests: Emergency care for unconscious patients.

• Public Task / Legal Obligation: Notifiable disease reporting (e.g., Meningitis, HIV).

• Legitimate Interests: Hospital administration / audit (sometimes).

• Key: You don't always need consent for routine care, but you need a lawful basis.

## Informed Consent Requirements

Freely Given: No coercion.

Specific: Consent for "treatment" is not consent for "research.„

Informed: Patient understands risks/benefits.

Unambiguous: Clear affirmative action (Opt-in).

Withdrawal: Patients can withdraw consent at any time without penalty

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# Patient Rights (Data Subjects)

- Right of Access: View their own medical chart.
- Right to Rectification: Correct errors in their medical history.
- Right to Erasure: Limited in healthcare (Medico-legal records must be kept for specific periods).
- Right to Restriction: Limit who sees specific data

**Exercise: Clinical Data Quiz**

1.Is a Medical Record Number (MRN) considered personal data? (Yes)

2.Can you access a neighbor's file just to check if they are okay? (No - Breach of confidentiality)

3.Does "Vital Interest" apply if a patient is awake and refuses care? (No)

**Task: Emergency Scenario**

Scenario: An unconscious patient arrives with no ID.
You need to run blood tests and check biometrics.

• Question: What is the lawful basis?

•Answer: Vital Interest. Consent is impossible, but processing is necessary to save a life.

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## Data Protection by Design

Default Security: Systems should be secure out-of-the-box.
Access Control: Role-Based Access (Students see less than Consultants).
Audit Trails: Every click in an EHR is logged.




## Pseudonymization in Research

1.Technique: Separating data from direct identifiers.
2.Key Management: The "Key" file linking Code <-> Name is kept secure and separate.
3.Re-identification: Only done if a safety alert requires contacting the patient.
4.Clinical Trial Regulation (CTR): Mandates this for participant protection.

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# Encryption

At Rest: Encrypting hard drives (BitLocker) and USBs.
In Transit: Using HTTPS/TLS for web portals.
End-to-End: Secure messaging apps (Signal/Institutional Pagers).

Rule: **If a device leaves the hospital, it MUST be encrypted**.

*Case Study: Redaction Failure*

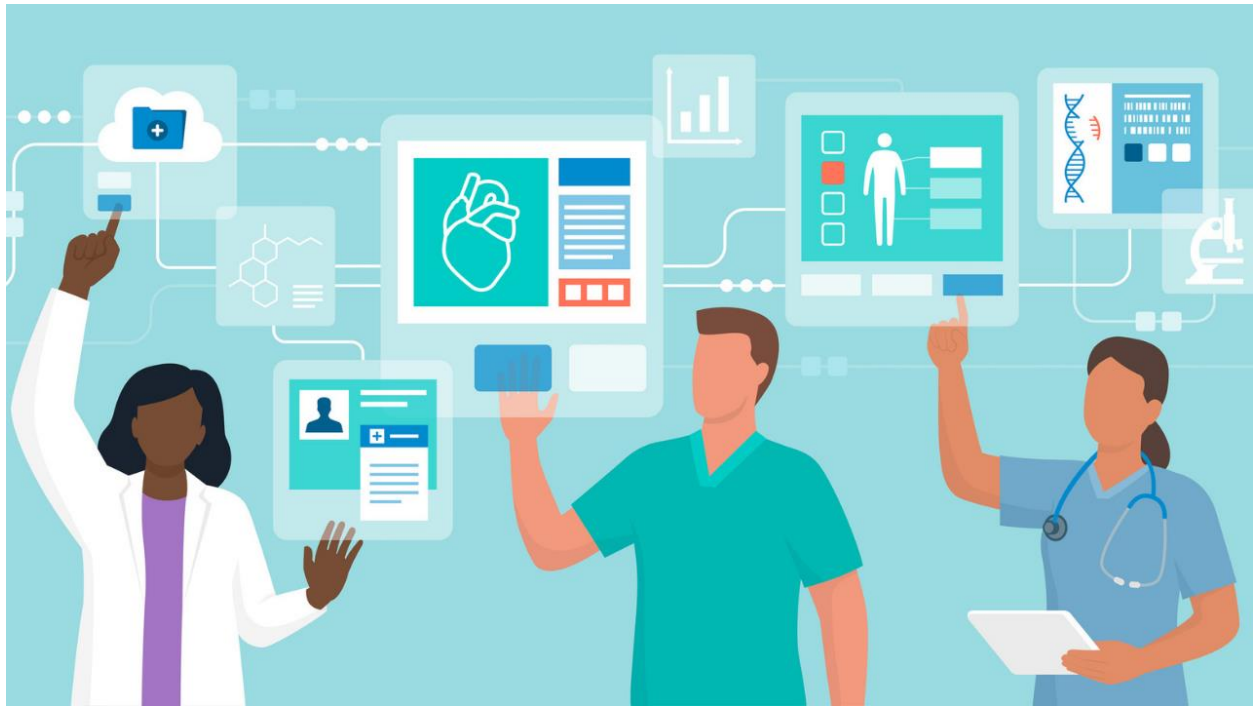
The Mistake: Using simple black/blue boxes in Word/PDF to "hide" names.
The Risk: Often reversible by copy-pasting or removing layers.
The Solution: Use dedicated "Redact" tools in PDF software that permanently remove the underlying text/pixels.

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# Secure Data Sharing

- **DO:** Use institutional secure email (e.g., NHSmail, hospital encryption portals).
- **DO:** Verify the recipient's identity before sending.
- **DON'T:** Send patient lists to your personal email to "work from home."
- **DON'T:** Share passwords or smartcards.



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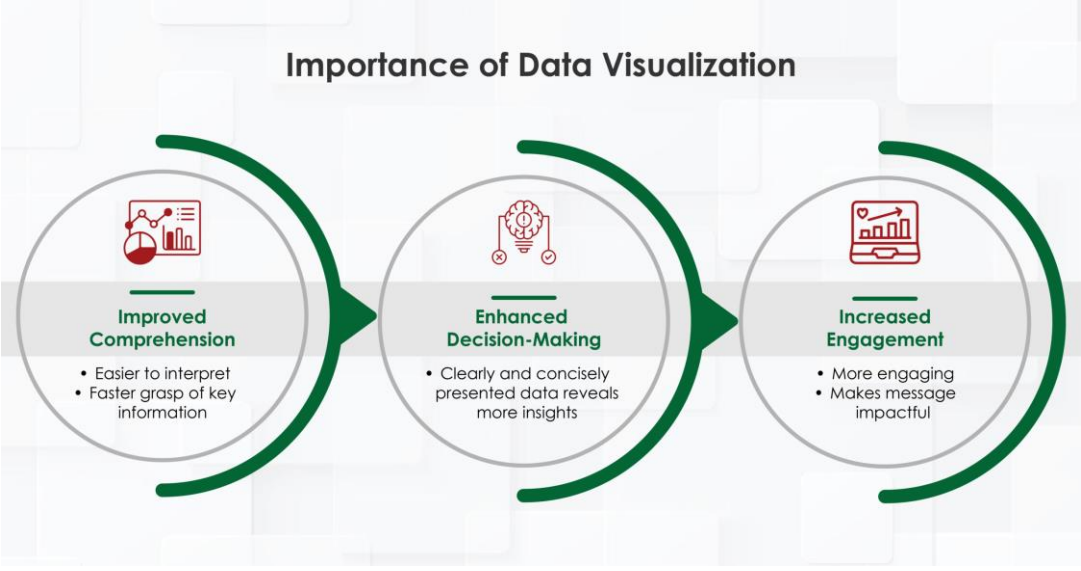
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# Presentation of Health Data

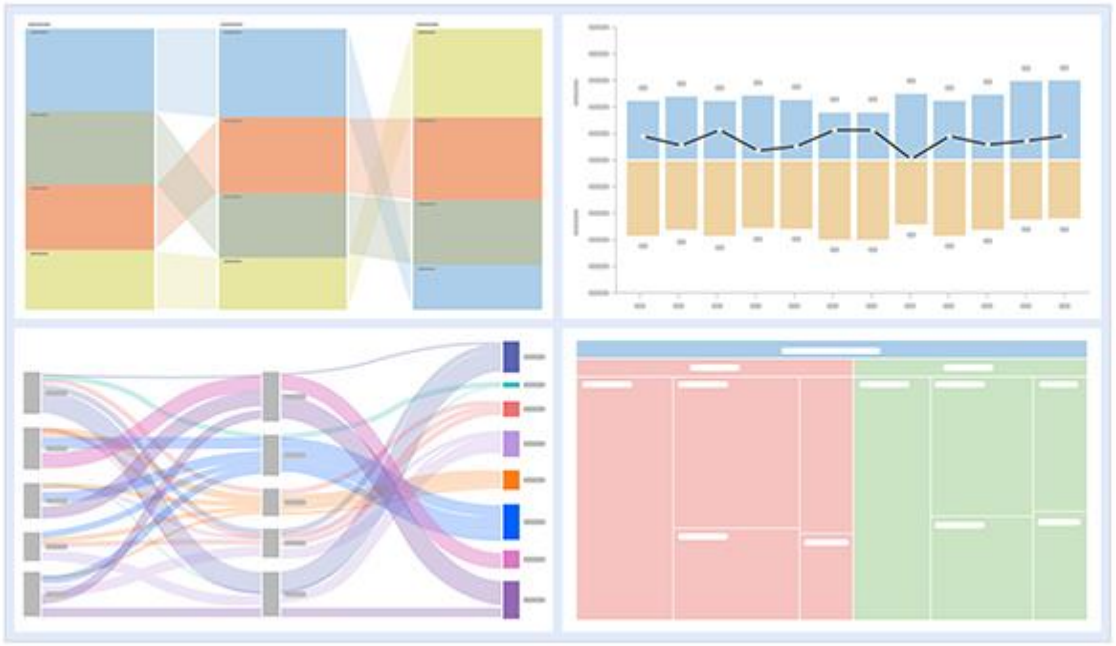
Critical Appraisal Skills for Clinicians
How to spot misleading data in pharmaceutical marketing and journals.

## Common Medical Visualizations

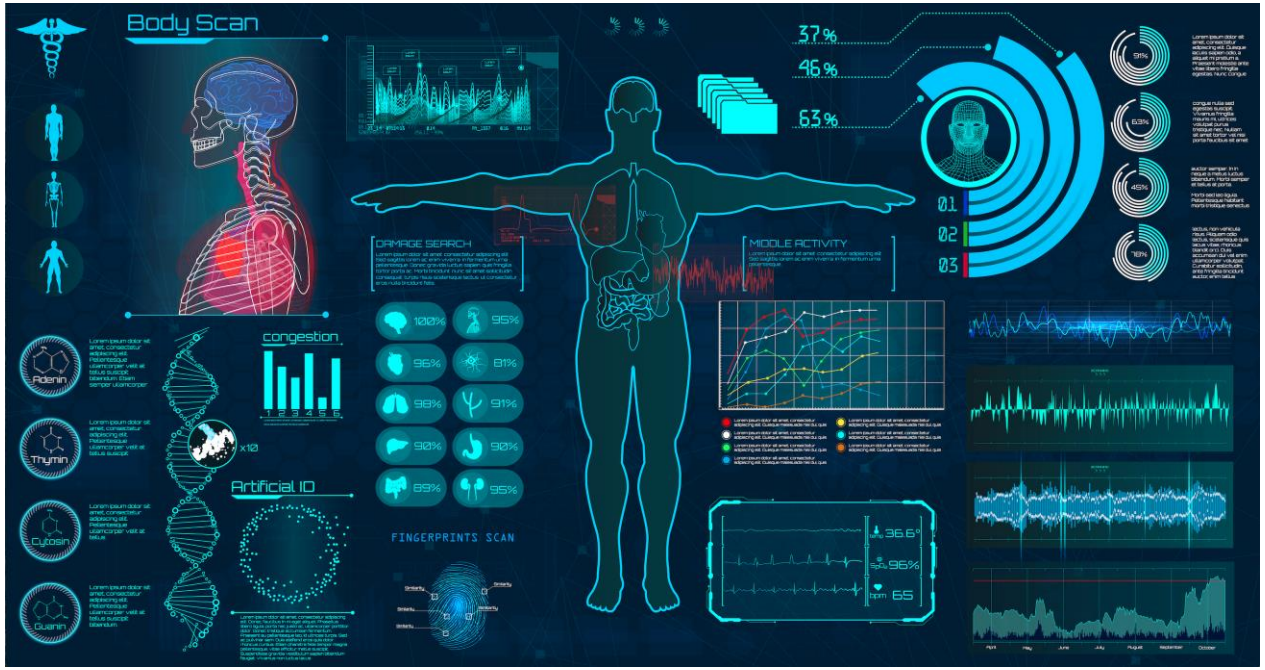
Kaplan-Meier Curves: Survival analysis over time.
Forest Plots: Meta-analysis results (Odds Ratios).
Box Plots: Distribution of lab values.
Infographics: Patient education materials (Use with caution).




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How to Get Started With Healthcare Data Visualization?

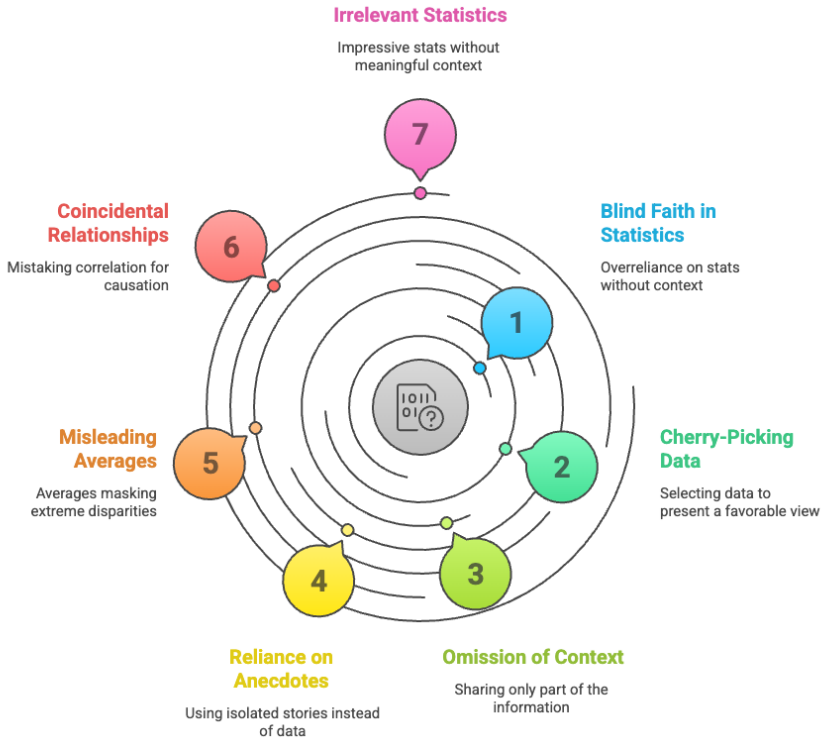



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# How Data Can Mislead (Pharma Tricks)

- ❑ Truncated Y-Axis: Exaggerating small differences between drugs.
- ❑ Relative vs. Absolute Risk: "50% risk reduction" sounds better than "Risk drops from 2% to 1%".
- ❑ Cherry-picking: Showing only the successful subgroup analysis.
- ❑ P-Hacking: Manipulating data until
- • $p<0.05p < 0.05p<0.0$

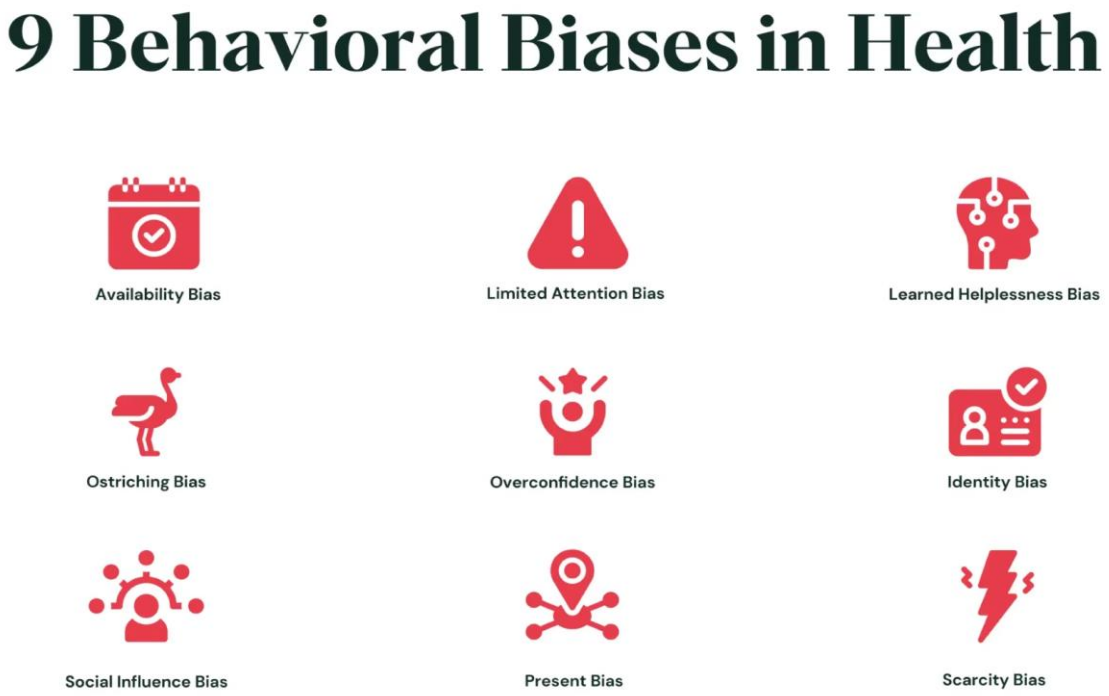



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# Cognitive Biases in Medicine

- Confirmation Bias: Trusting data that fits your diagnosis; ignoring data that doesn't.
- Availability Heuristic: Overestimating rare diseases because you saw a case recently.
- Survivorship Bias: Looking only at patients who returned for follow-up (ignoring those who died or dropped out).




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# Conclusion

Competency: Handling data is a core clinical skill.

Ethics: Protect patient privacy as fiercely as you protect their health.

Skepticism: Always critically appraise data visualizations and statistics.

Action: Apply ALCOA+ and Privacy by Design in your daily rotations.

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