Artificial Intelligence for Patient Data and Drug Safety: Insights for Safer Care

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Evidence-Based Medicine Research & Pharmacovigilance Training

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Objectives

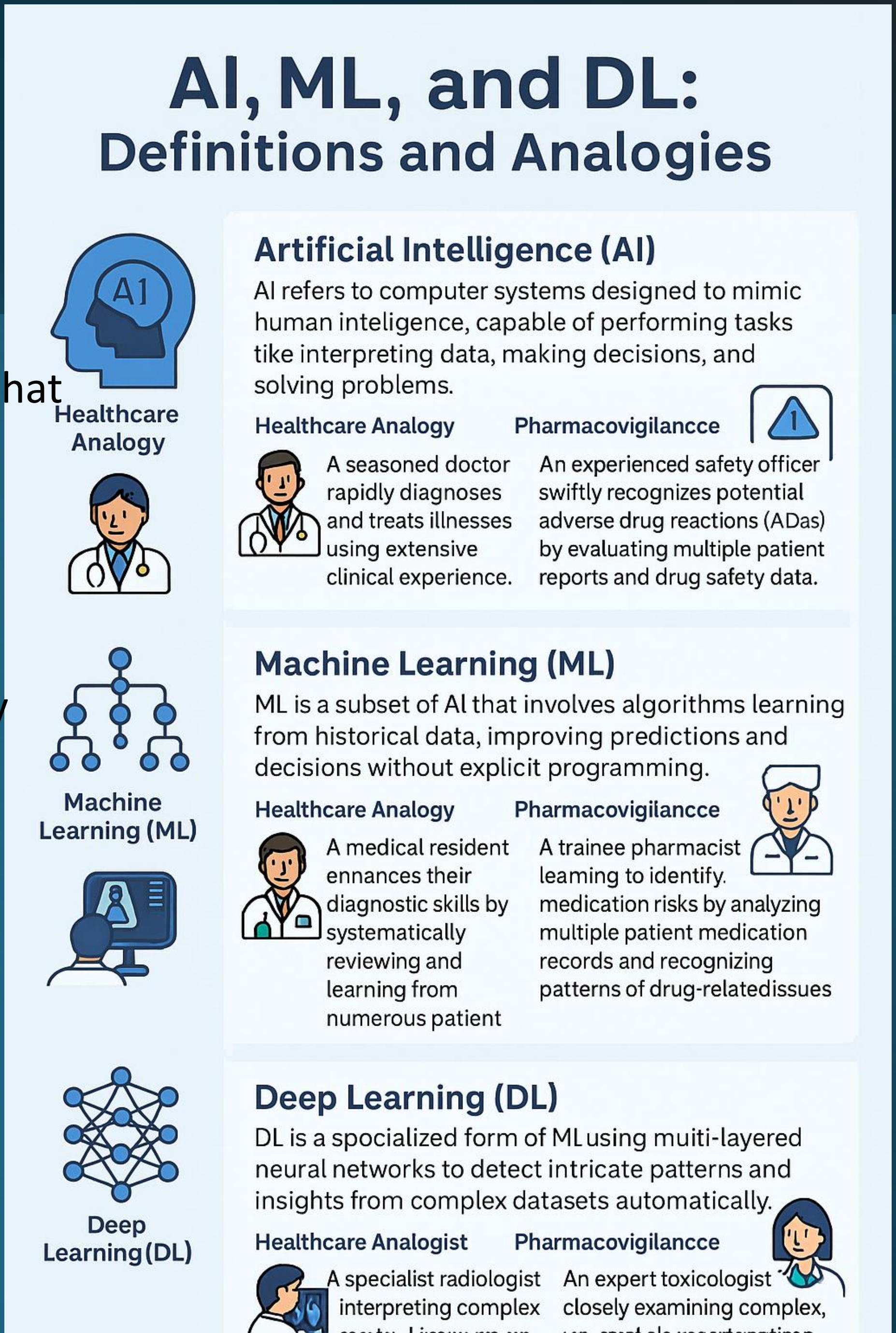
Understand	Understand AI and ML fundamentals in healthcare
Identify	Identify types and sources of patient data
Apply	Apply basic AI techniques
Interpret	Interpret AI outputs
Address	Address ethical and privacy concerns

Presentation Outline

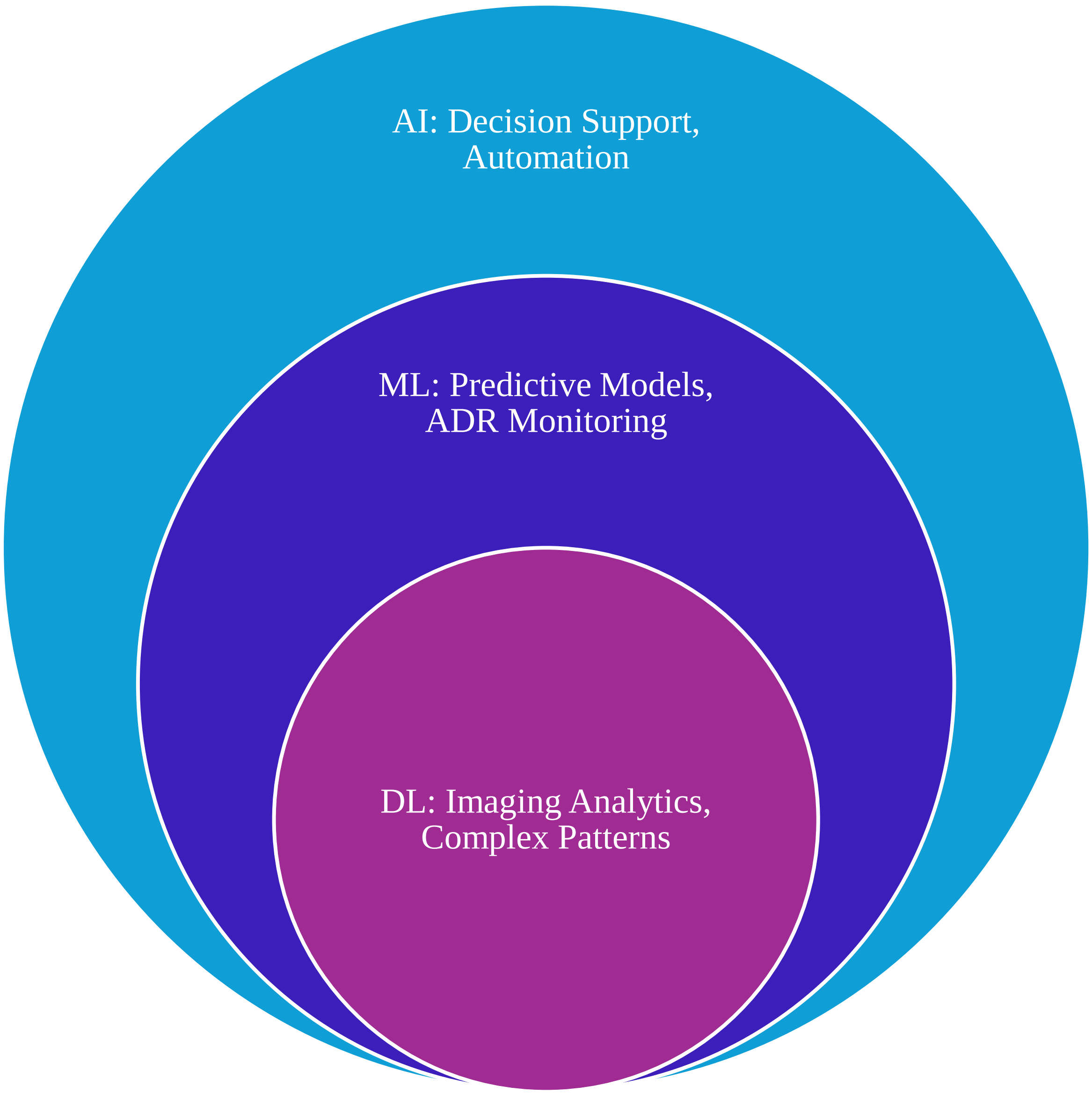
- Introduction to AI, machine learning (ML), and deep learning (DL)
- Overview of AI applications in healthcare
- Types of patient data: structured vs unstructured
- Data quality, bias, and preprocessing in healthcare datasets

Healthcare Analogy: A specialist radiologist interpreting complex medical images to identify subtle and nuanced abnormalities that others may overlook.

Pharmacovigilance Analogy: An expert toxicologist closely examining complex, detailed clinical narratives to detect rare, subtle, or previously unreported drug safety signals.



Relationship between AI, ML, and DL



AI Applications in Healthcare

Diagnostic imaging

Predictive analytics (patient outcomes, readmissions)

Pharmacovigilance using NLP

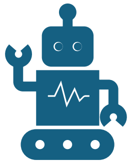
AI supports clinicians with data-driven decision-making.

Enables faster, more targeted diagnostics and interventions.

Moves healthcare from reactive to proactive care.

Think of AI as a clinical assistant trained on millions of cases.

Case 1: Diagnostic Imaging AI



AI model detects COVID-19 signs from X-rays.

Flags critical scans before the radiologist reviews them.

Patient receives immediate ICU care and recovers.

Raises questions: responsibility, accuracy, and trust.

Discussion – Case 1

- How did AI improve patient outcomes?
- Who makes the final call: AI or clinician?
- What are the risks if AI is wrong?
- Raises questions: responsibility, accuracy, and trust.

Case 2: Predictive Analytics (Readmission)

ML model predicts 30-day readmission risk.

Flags elderly diabetic patient with poor discharge vitals.

Follow-up nurse assigned; readmission prevented.

Demonstrates predictive care and prevention.

Discussion – Case 2

- What patient factors might the AI use?
- How does this support preventive care?
- What data privacy or bias risks exist?

Case 3: NLP in Pharmacovigilance

- NLP scans social media and patient feedback.
- Detects unexpected side effects of hypertension drug.
- ADR signal escalated for regulatory review.
- Faster detection than traditional reporting methods.

Discussion – Case 3

- Could this be detected using traditional methods?
- How are human experts involved in signal validation?
- What are the implications for regulatory action?

Definitions and Examples of Structured and Unstructured Data

Structure Patient Data

a. Organized into rows and columns (e.g., databases, spreadsheets).
b. Easily searchable, analyzable, and standardized.
c. Examples: EHR tables, lab results, vitals, and medication records.
d. Dataset Example: MIMIC-III database (ICU patient data).

Unstructure Patient Data

a. Free-form data without a pre-defined structure.
b. Challenging to analyze directly without NLP, imaging, or audio processing.
c. Examples: Physician notes, radiology images, audio dictations.
d. Dataset Example: Sample clinical notes or discharge summaries from MIMIC-III.

Structured vs. Unstructured Data

Structured Data

Highly organized information stored in predefined formats like tables or databases

Blood pressure = 120/80 mmHg

- Laboratory test results HbA1c = 6.2%
- Medication lists and dosages

Unstructured Data

Information not stored in a predefined data model or format

"Patient complains of chest tightness and fatigue..."

Radiology images

Voice recordings

Examples of both structured and unstructured patient data types,

🧾 Structured Data (Tabular Format)

Patient ID	Temp (°C)	BP (mmHg)	Heart Rate (bpm)	Diagnosis Code	Medication	Lab Result
001	37.2	120/80	82	I10	Atenolol	HbA1c = 6.4
002	38.0	135/85	90	J20	Azithromycin	WBC = 11.2
003	36.6	115/70	75	E11	Metformin	Glucose = 140

Unstructured Data (Free Text Narrative)

- **Example 1 – Physician Note:**
  “Patient reports fatigue, shortness of breath, and mild fever. Vitals stable. Suspect early-stage infection. Plan: start empirical antibiotics and monitor for 48 hours.”
- **Example 2 – Adverse Drug Reaction Report (Patient):**
  “Since I started the new blood pressure medicine, I’ve been feeling dizzy in the mornings. Sometimes I get a rash on my arms, too.”
- **Example 3 – Audio Transcription (Consultation Summary):**
  “Patient says they’re tolerating Metformin but occasionally feel nauseated after meals. No signs of hypoglycemia reported.”

Common dataset issues with examples and fixes from real datasets

Issue	Why It Matters in Pharmacovigilance / Medicine	Typical Example	Practical Fixes & Mitigation
Missing values	Spontaneous safety reports (ICSRs) or EHR extracts may lack dose, onset date, or lab confirmation—hampering signal detection and case assessment.	12 % of Individual Case Safety Reports omit **time-to-onset**, making disproportionality analysis less reliable.	• **Follow-up queries** to reporters / clinicians. • **Domain-aware imputation** (e.g., impute onset date from median latency in similar cases). • Flag "critical missing fields" to rout cases for manual review before database lock.
Noise & outliers	Implausible doses, negative ages, or duplicate MedDRA codes inflate or mask drug–event signals.	Dose recorded as "50 000 mg" instead of "50 mg" triggers a false safety alert.	• **Range rules & units checks** at point of data entry. • **Automated outlier detection** (IQR/Z-score) followed by pharmacovigilance-expert review. • Maintain a **drug-specific plausibility table** (e.g., maximum daily oral dose).
Duplicate records	The same ADR case can flow into EV/FAERS from multiple reporters; duplicates over-count events and bias disproportionality metrics.	A hospital EHR export and a spontaneous report both describe the identical anaphylaxis case—counted twice in signal analysis.	• **Deterministic / probabilistic de-duplication** using patient initials + age + event date + drug. • Apply **WHO UMC vigiMatch** or similar duplicate-detection algorithms.
Bias – Selection – Measurement – Demographic	Skewed case mix distorts risk estimates and ML model performance.	**Selection:** 80 % of ADR reports come from tertiary hospitals—community reactions are under-captured. **Measurement:** A new e-reporting app asks for "severity" on a 1–3 scale, and an older paper form uses SOC codes to shift the severity distribution. **Demographic:** Under-reporting in paediatrics yields sparse safety data for children.	• **Post-stratification weighting** or **inverse-probability weighting** when analysing signals. • Harmonise data-collection instruments; apply **calibration factors** if devices/scales change. • Targeted awareness campaigns to boost reporting in under-represented groups (e.g., paediatrics, geriatrics).

Data Preprocessing Techniques in Medicine & Pharmacovigilance

Preprocessing transforms raw, inconsistent data into clean, reliable input for meaningful analysis and AI models.

1. Data Cleaning 🧹

Goal: Remove errors, fill gaps, and correct inconsistencies.

Task	Example (Pharmacovigilance/Medicine)	Why It Matters
Missing value handling	Fill in missing age in ICSR with median from similar reports	Prevents model distortion or analysis errors
Outlier removal	Remove Metformin dose = 50,000 mg	Prevents false signal detection or clinical misinterpretation
Duplicate detection	Same ADR case reported by hospital and pharmacy	Avoids overcounting in signal detection
Inconsistent units	Normalize "2 g" vs "2000 mg" to same unit	Ensures uniformity in dose-response analysis

PowerBI (Business Intelligence)

What is Power BI? – One Slide Overview

Facilitator: Dr. Sakinat Folorunso

Key Features

- Connect to data (Excel, CSV, SQL, cloud)
- Interactive visuals (charts, KPIs, maps)
- Data cleaning with Power Query
- AI features: Key Influencers, forecasting
- Build dashboards & share insights

Versions

- Power BI Desktop (Free, Windows app)
- Power BI Service (Pro/Premium for sharing)
- Power BI Mobile (view dashboards)

⚕ Uses in Healthcare

- Analyze patient data & outcomes
- Monitor Adverse Drug Reactions (ADRs)
- KPIs: Readmission %, Mortality %, LOS
- Share dashboards for decision support

Power BI turns raw data into clear, interactive stories for better decision-making.

PowerBI (Business Intelligence)

□ Power BI Desktop Quick Start – One Slide

Facilitator: Dr. Sakinat Folorunso

1□ Download

□ Microsoft Store OR

□ https://aka.ms/pbiSingleInstaller

2□ Install & Open

⚙ Setup wizard

▶ Start Menu → Power BI Desktop

3□ First-Time Setup

□ Sign in OR 'Skip for now'

4□ Load Data

□ Home → Get Data → Excel/CSV → Load

5□ Build Visuals

□ Pick visual (bar, line, KPI, map)

□ Drag fields to Axis/Values/Legend

6□ Create Report Pages

□ Multiple visuals per page

□ Add slicers (filters)

7□ Save & Share

□ Save as .pbix

☁ Publish to Power BI Service

Quick reference – Power BI essentials in one slide

Why Power BI Works for Healthcare & Pharmacovigilance

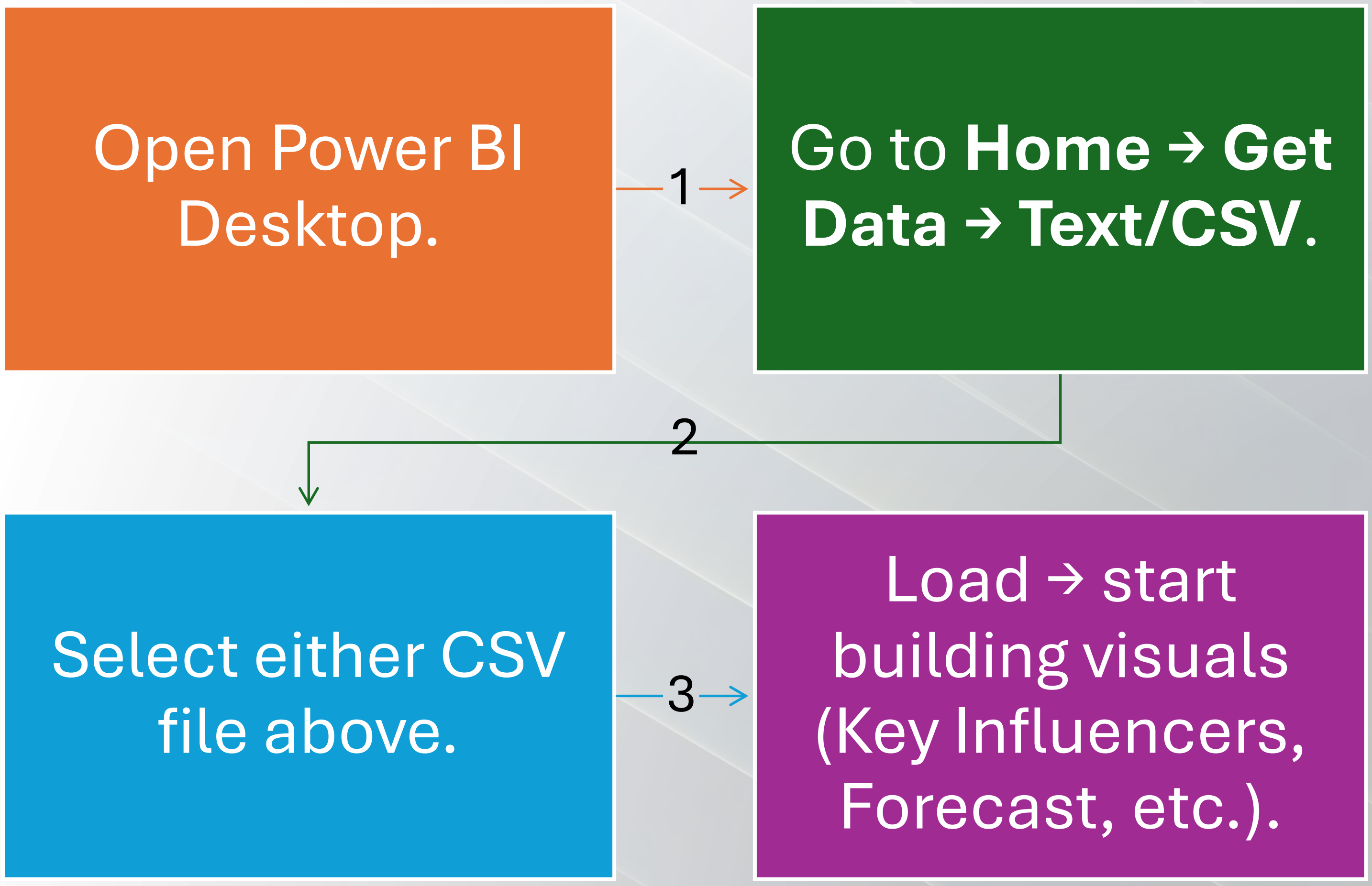
- Low learning curve.
- Handles structured patient data
- Built-in AI/ML features
- Visualization-first
- Integration

Simple AI Features in Power BI

Key Influencers Visual	Automatically shows which factors (e.g., age, dosage, comorbidities) influence outcomes like adverse drug reactions.
Decomposition Tree	Lets users explore data hierarchically (e.g., ADR by drug class → hospital → age group).
Forecasting & Trend Analysis	Time series forecasting for patient admission rates, adverse drug reports over months.
Q&A (Natural Language Queries)	Participants can *type questions* like *“Which drug had the highest number of side effects in 2024?”* and Power BI generates a visual.
Quick Insights	Power BI can scan datasets and highlight anomalies, trends, and correlations automatically.

Fast Power BI Demo (step-by-step)

How to use **Power BI**:



What we'll build in Power BI

3 visuals:

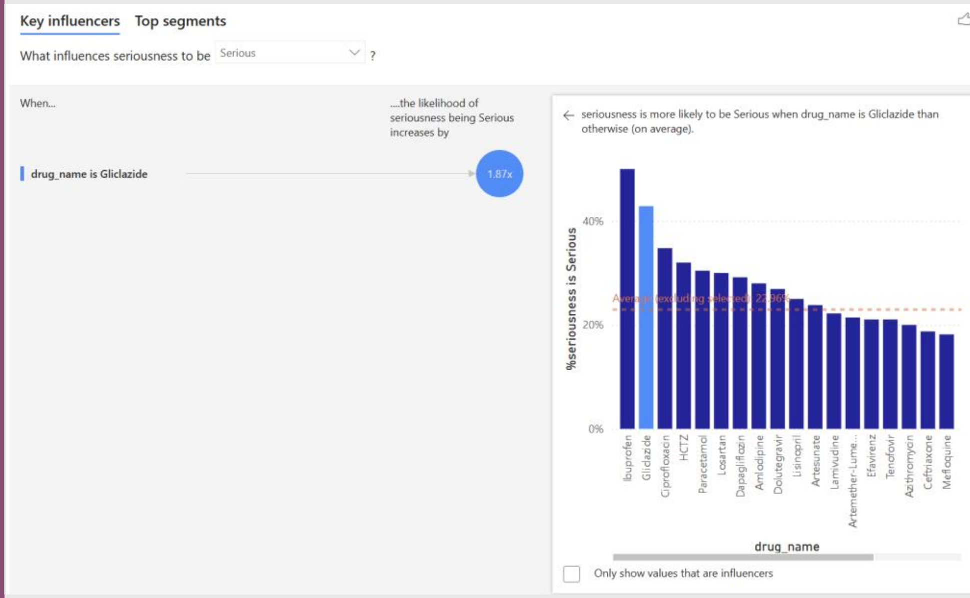
Key Influencers (risk drivers)

Trend forecast

Decomposition Tree

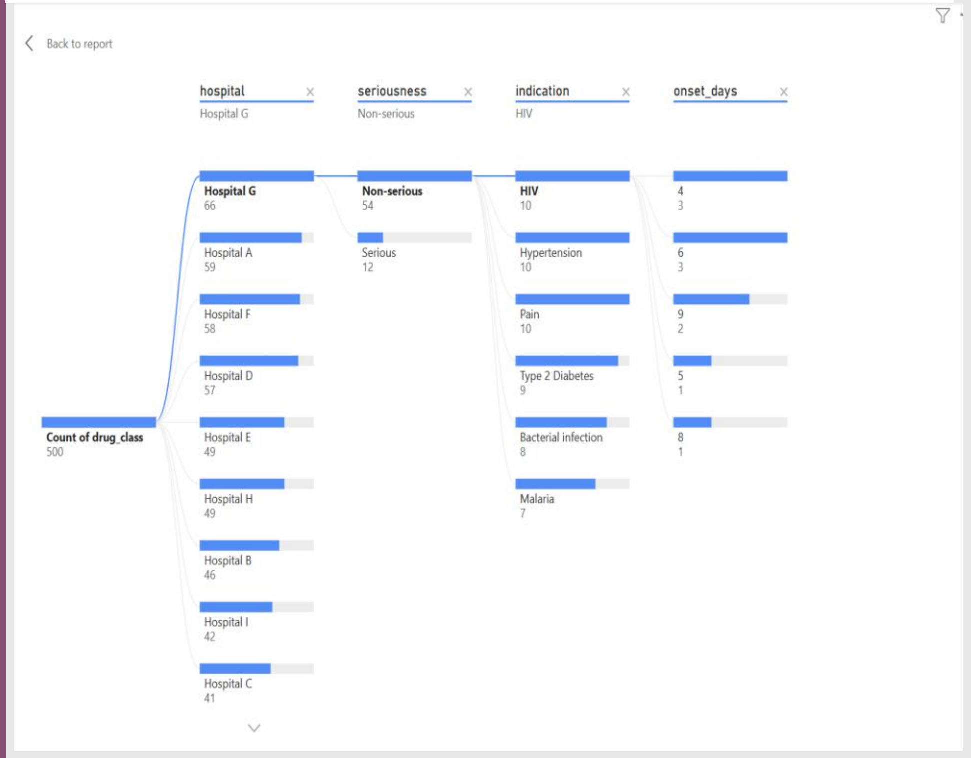
Key Influencers (Risk drivers) – Pharmacovigilance

1. Load *pharmacovigilance_adr_reports.csv.*
2. Insert **Key Influencers** visual.
3. *Analyze:* `seriousness` (treat "Serious" vs "Non-serious" as outcome).
4. *Explain by:* `age`, `dosage_mg`, `drug_class`, `event_type`, `sex`, `onset_days`, `causality_score`, `concomitant_meds_count`, `state`.
5. Talking point: dose, age ≥65, and specific **drug classes** emerge as top drivers → *clinical risk flags* for pharmacovigilance.



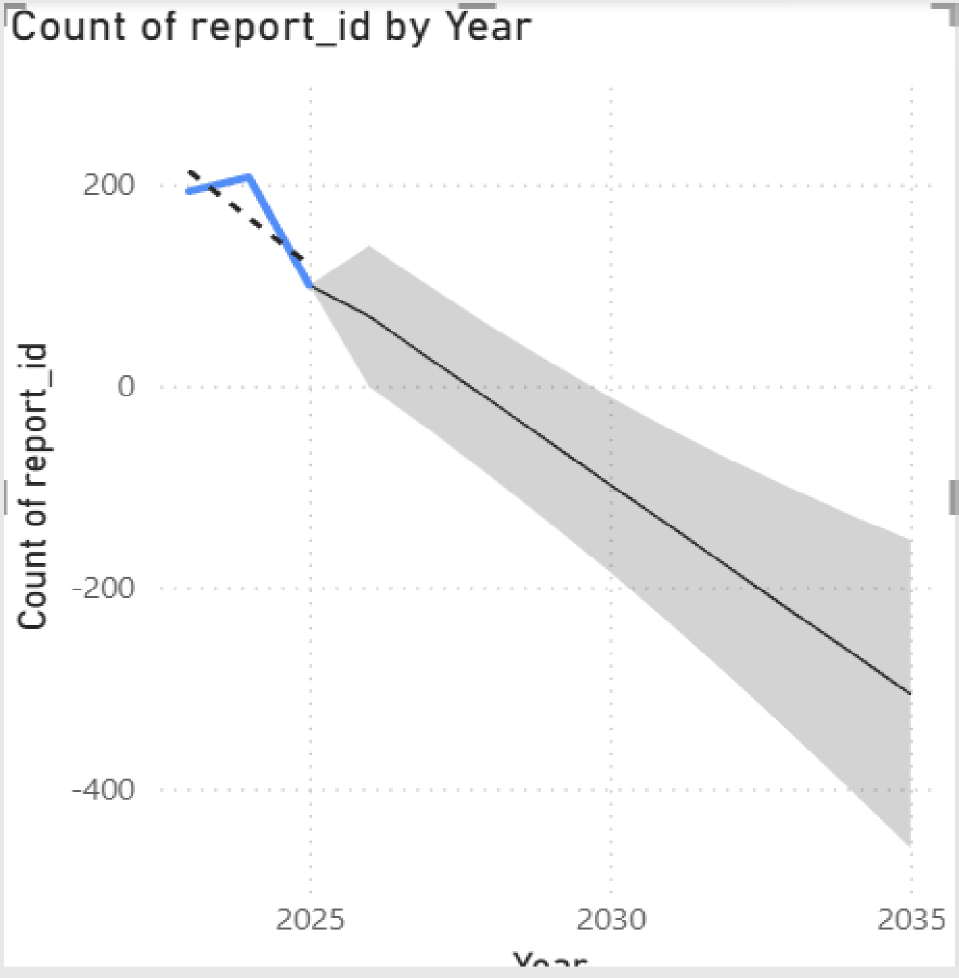
Decomposition Tree (Drill-downs) – Pharmacovigilance

1. Add Decomposition Tree.
2. Root: `count of report_id`.
3. Drill by: `drug_class → hospital → age → seriousness`.
4. Talking point: quickly locate **clusters of serious ADRs** by hospital/drug class.



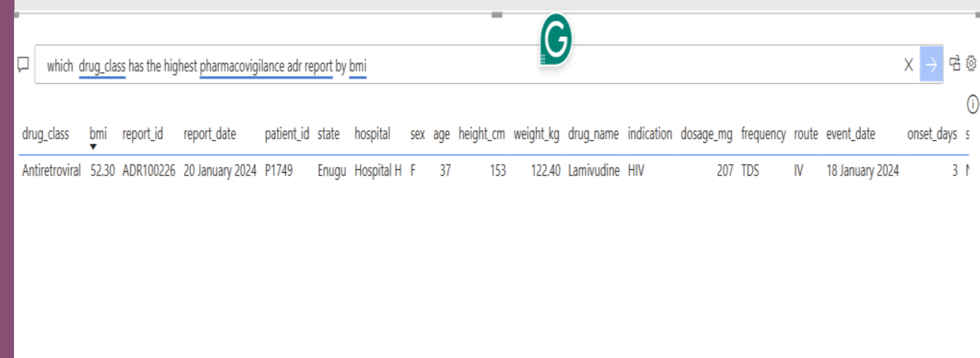
Forecasting (Trends) – Pharmacovigilance

1. Create a **line chart**: `report_date` (Axis) vs `count of report_id` (Values).
2. Turn on **Analytics → Forecast** (e.g., 6–12 steps).
3. Talking point: show **seasonal spikes** or **post-policy changes** in reports.



Q&A (Natural language) – Both datasets

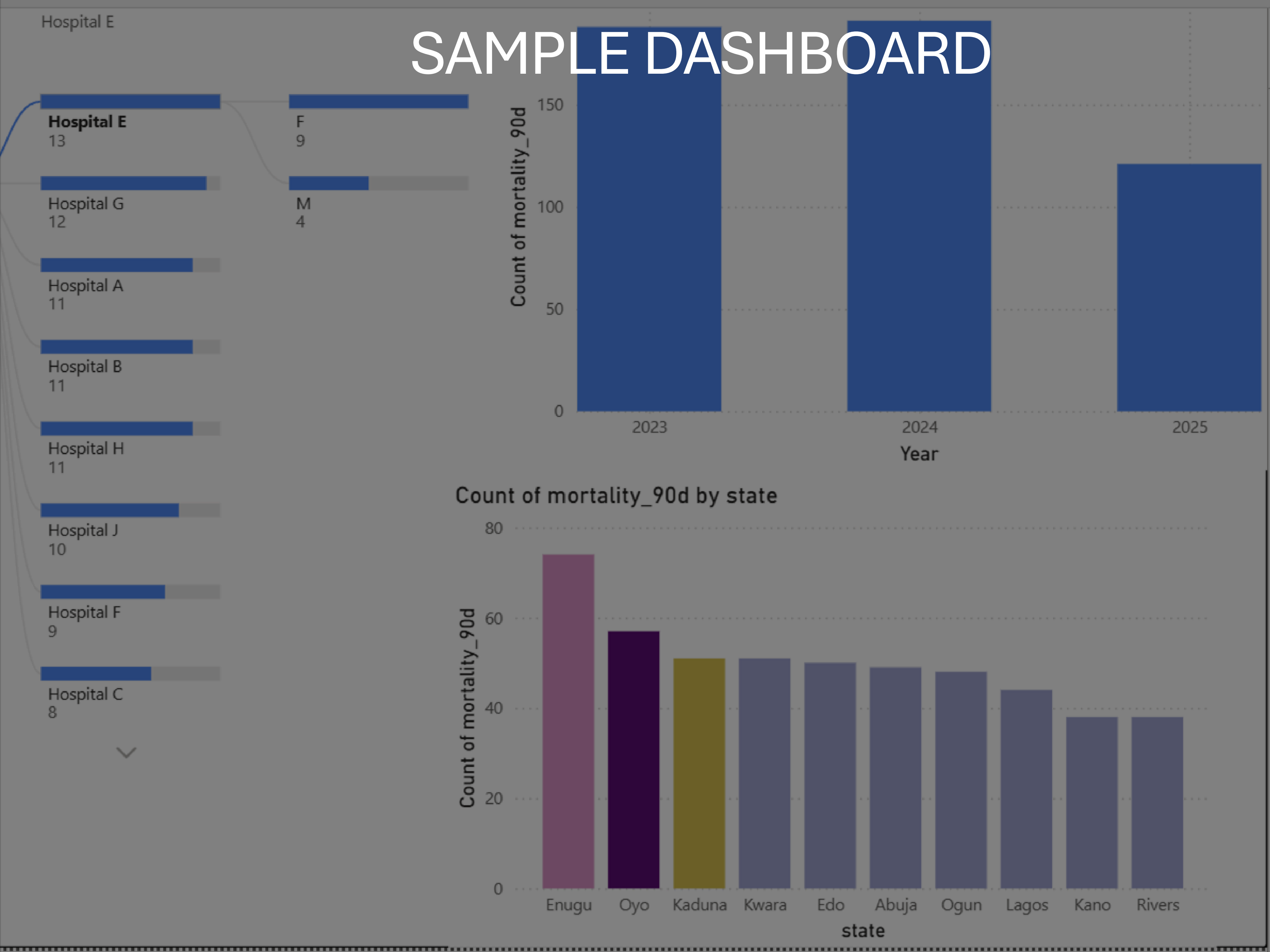
- Enable **Q&A** and ask:
  - *"Which drug class has the highest number of serious events in 2024?"*
  - *"Show average length_of_stay_days by diagnosis in 2025."*



drug_class	bmi	report_id	report_date	patient_id	state	hospital	sex	age	height_cm	weight_kg	drug_name	indication	dosage_mg	frequency	route	event_date	onset_days
Antiretroviral	52.30	ADR100226	20 January 2024	P1749	Enugu	Hospital H	F	37	153	122.40	Lamivudine	HIV	207	TDS	IV	18 January 2024	3

Outcomes Dashboard – Medicine

1. Load *medicine_patient_outcomes.csv*.
2. Cards: average `length_of_stay_days`, `% readmission_30d`, `% mortality_90d`.
3. Bar chart: `diagnosis` vs `readmission_30d` rate.
4. Key Influencers: **Analyze** `readmission_30d` → **Explain by** `age`, `lab_abnormalities_count`, `creatinine_mg_dl`, `ALT_U_L`, `hemoglobin_g_dl`, `dosage_intensity`, `length_of_stay_days`, `diagnosis`.
5. Talking point: **lab abnormalities + age** drive readmissions → targets for care pathways.


SAMPLE DASHBOARD
Hospital E
Hospital E
13
Hospital G
12
Hospital A
11
Hospital B
11
Hospital H
11
Hospital J
10
Hospital F
9
Hospital C
8
F
9
M
4
Count of mortality_90d
150
100
50
0
2023
2024
2025
Year
Count of mortality_90d by state
80
60
40
20
0
Count of mortality_90d
Enugu
Oyo
Kaduna
Kwara
Edo
Abuja
Ogun
Lagos
Kano
Rivers
state

Simple Cohort Filter (Slicers) – Both

- Add slicers for `state`, `hospital`, `sex`, `age` (numeric range) to simulate **site-level pharmacovigilance** or **ward-level audit**.

Training Demo Flow with Power BI

Dataset Import – Load a CSV of patient vitals + drug history + adverse reactions.

Data Cleaning – Show missing value handling and transformations (link to data quality/bias lecture).

Visualization – Build basic charts (adverse events by drug, hospital, age).

AI Insights – Apply *Key Influencers* + *Q&A* + *Forecasting*.

Interpretation – Discuss how clinicians can use these insights for pharmacovigilance decisions.

Clinical Interpretation

Bullet point example: “High dosage_mg + age ≥65 → increased ‘Serious’ ADR. Consider dose review and monitoring.”

Ethical Issues in AI for Pharmacovigilance & Healthcare

Informed Consent

Patients must be fully aware of how their medical data is used, especially in AI research.

Bias and Fairness

AI systems should avoid favoring certain groups or others, ensuring equitable outcomes,

Interpretability and Transparency

AI predictions must be understandaable and justifiable to clinicians and regulators.

NDPR & WH Alignment

AI use must align with Nigeria Data Protection Regulat (NDPR) and WH guidelines

Ethics & Privacy

“De-identify, aggregate; follow NDPR/HIPAA; restrict direct identifiers.”

Data Quality & Bias

Check missing labs

class imbalance (few fatal cases)

site reporting bias (some hospitals under-report)

Closing & Takeaways

AI is a *tool*, not a replacement for medical expertise.

Patient data must be used responsibly.

Evidence-based practice + AI = stronger pharmacovigilance