Cloud Computing Is Poised to Spur the Use of Real-World Data in Healthcare

Usman Qazi, PhD
Independent Consultant
Life Sciences Strategy

Talk Organization

- Real-World Data and Evidence
- Overview of Cloud Computing
- Examples of GCP Architecture for Healthcare Applications

Sources: Interviews with cloud experts. Clinical and trade journal literature. My own cloud experience on GCP.

Speaker Introduction

- Independent consultant working in life sciences market strategy.
  - Therapeutics, medical devices, imaging.
- Clients have ranged from start-ups to big pharma.
- Academic background in 3D electron microscopy of proteins
- Currently studying cloud platforms for new opportunities.

www.linkedin.com/in/uqazi

What is the current state of real-world data and evidence?

Real-world evidence is a recent paradigm for regulatory agencies

- Real World Data (RWD) relate to patient health status and/or the delivery of health care… [FDA].

  - Electronic health records (EHRs), medical claims and billing data, product and disease registries, patient-generated data, data gathered from mobile devices.

  - Clinical Real World Evidence (RWE): Usage, and potential benefits or risks, of a medical product

    - Derived from analysis of RWD.

  - Enabled by 21st Century Cures Act (2016).

- Regulatory agencies in EU and Japan have somewhat equivalent definitions.

Where can RWE replace randomized controlled trials?

- *"RWE better reflects the actual clinical environments in which medical interventions are used, including patient demographics, comorbidities, adherence, and concurrent treatments."*
  - Feasibility of Using Real-World Data to Replicate Clinical Trial Evidence, JAMA Netw Open. 2019;2(10):e1912869 (2017).
- Only 15% of 220 selected published clinical trials could be replicated with RWE.
- Criteria for successful replication with EHRs, insurance claims, patient registries:
  - Well-defined indications and interventions.
  - Larger numbers of patients and recruitment sites.
  - Previous FDA approval.
- RWE studies will be boosted by improved observational protocols and data sources (pathology, medical device surveillance).

# How can clinical trial design be adapted to real-world data?

- Trial designs with RWE require pragmatic and large simple trials.

  - Include long-term follow up.

- Examples of drugs approvals with RWE:

  - For rare indications in oncology (Bavencio & Blincyto) using controls from RWD sources.

  - Longer acting form of schizophrenia drug (Invega)

    - Trial designs using real-world data: The changing landscape of the regulatory approval process. Pharmacoepidemiol Drug Saf. 2019;1–12.

IoT-enabled medical devices pose a 'big data' challenge

- Example: Low cost IoT-enabled ventilator from aerobiosys.com (India).
  - Alerts mobile app in case of issues like air leakage, power cuts or non-synchronous breathing by the patient.

RWD Source: FDA's mobile app for reporting outcomes
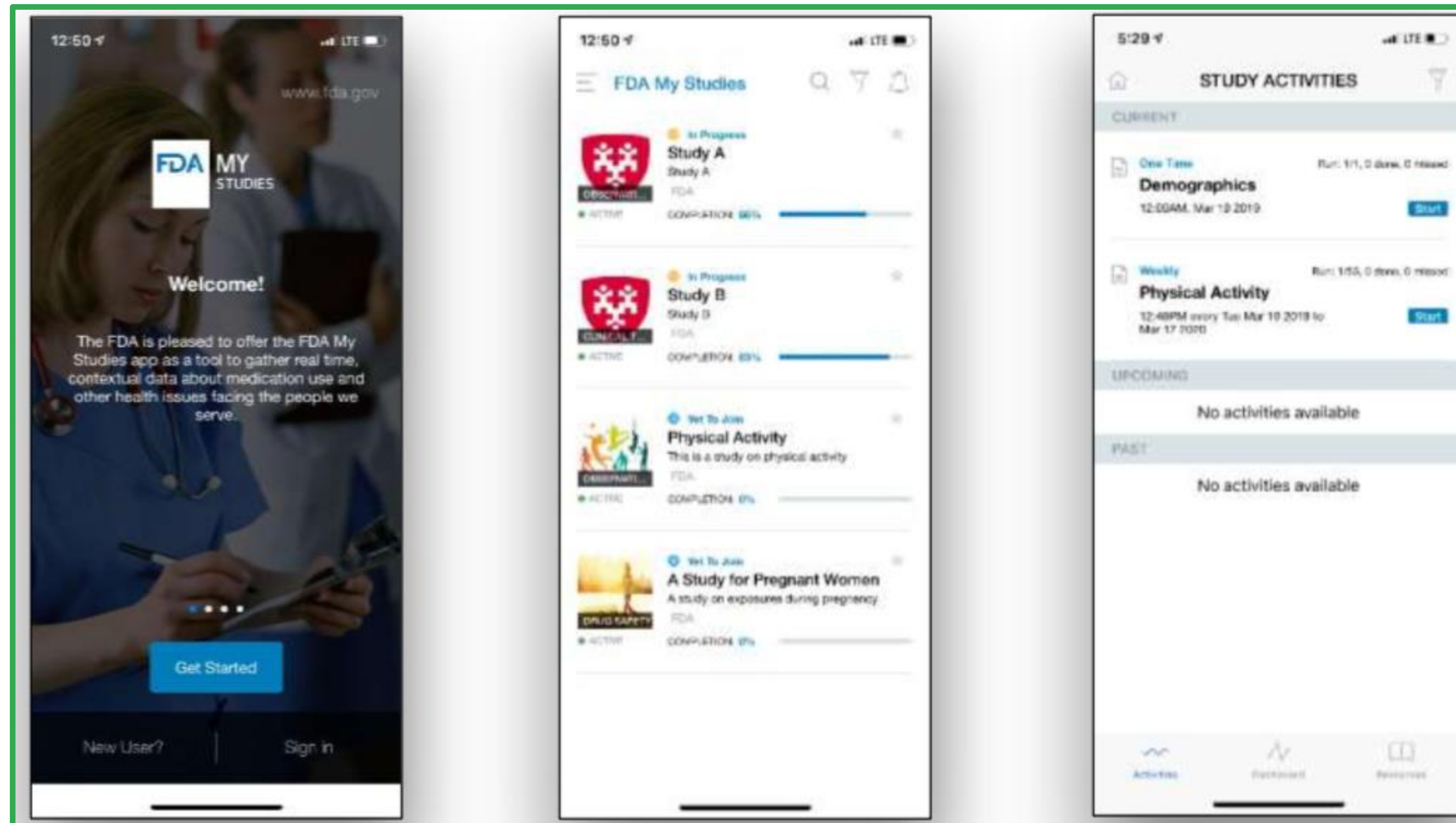
- MyStudies app is hosted on Google Cloud Platform.
- Example: Cardiomyopathy survey queries patients on showering/bathing.
- Template for Stanford Medicine's MyHeart Counts 3.0 trial.

FDA is vested in several data and cloud computing initiatives

- National Evaluation System for Health Technology focuses on leveraging RWE for medical devices.
  - Funded by medical device user fees.
- FDA is building a $100 million medical data enterprise system using EHR data from about 10 million people to build a foundation for more robust postmarketing studies.
- FDA is also establishing high-speed, secure connections from its data centers to cloud providers.
  - Starting with GovCloud (Amazon Web Services).
  - Aligned to federal cloud adoption and security initiatives (Cloud Smart and FedRAMP).

What are the advantages of cloud computing over on-premises big data technology?

Big data technology is traditionally built with on-premises or leased distributed computing infrastructure

- On-premise computing hardware is not easy to upgrade, improve for availability, or scale.

- Original software tools required considerable developer resources.

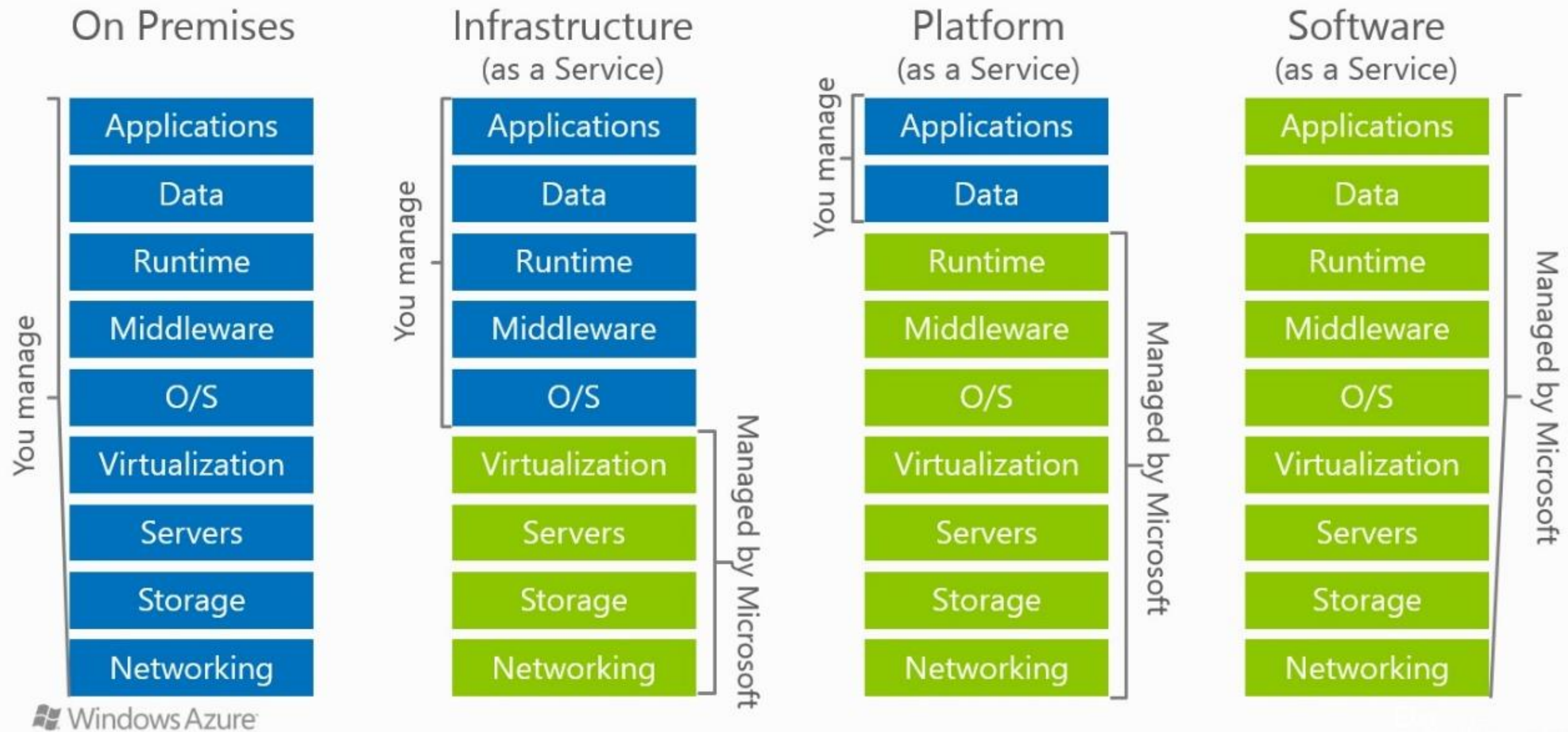- Traditionally preferred by organizations because of security.

Distributed Computing
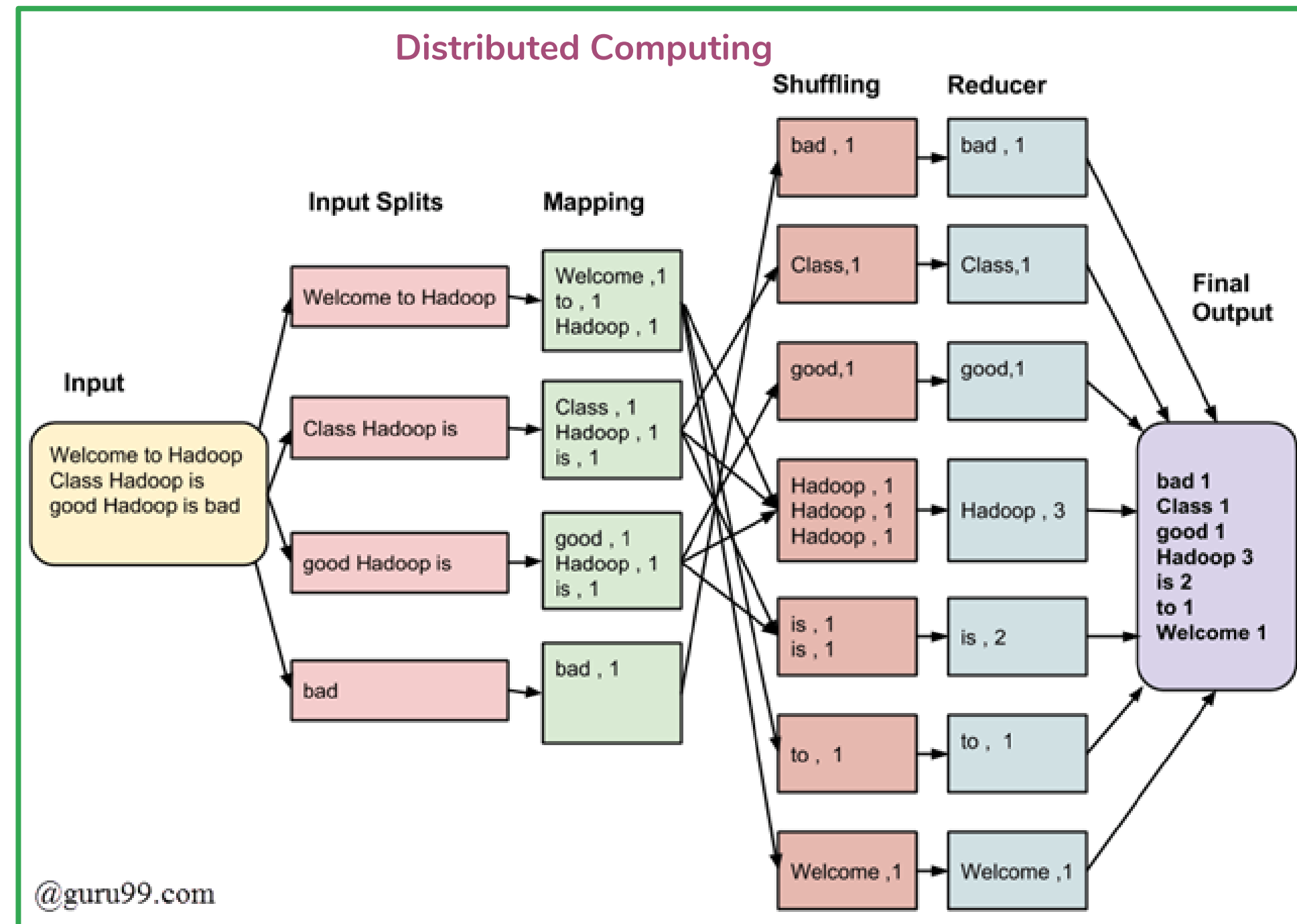
Cloud computing resolves challenges of big data technology

Big Data	Cloud
Server maintenance and upgrades	Managed services
Hardware	Virtual computing infrastructure that is scalable (elastic)
Original software tools	Library of curated, plug/play, open-source tools
Owner-ensured security	Owner and cloud provider both ensure security

Managed cloud services serve a range of user needs

Large players with global footprints dominate the cloud market

Amazon Leads $100 Billion Cloud Market

Worldwide market share of leading cloud infrastructure service providers in Q4 2019*

amazon web services — 33%
Microsoft Azure — 18%
Google Cloud — 8%
IBM Cloud — 6%
Alibaba Cloud — 5%
salesforce — 3%
ORACLE CLOUD — 2%
Tencent Cloud — 2%

Worldwide cloud infrastructure service revenue in 2019
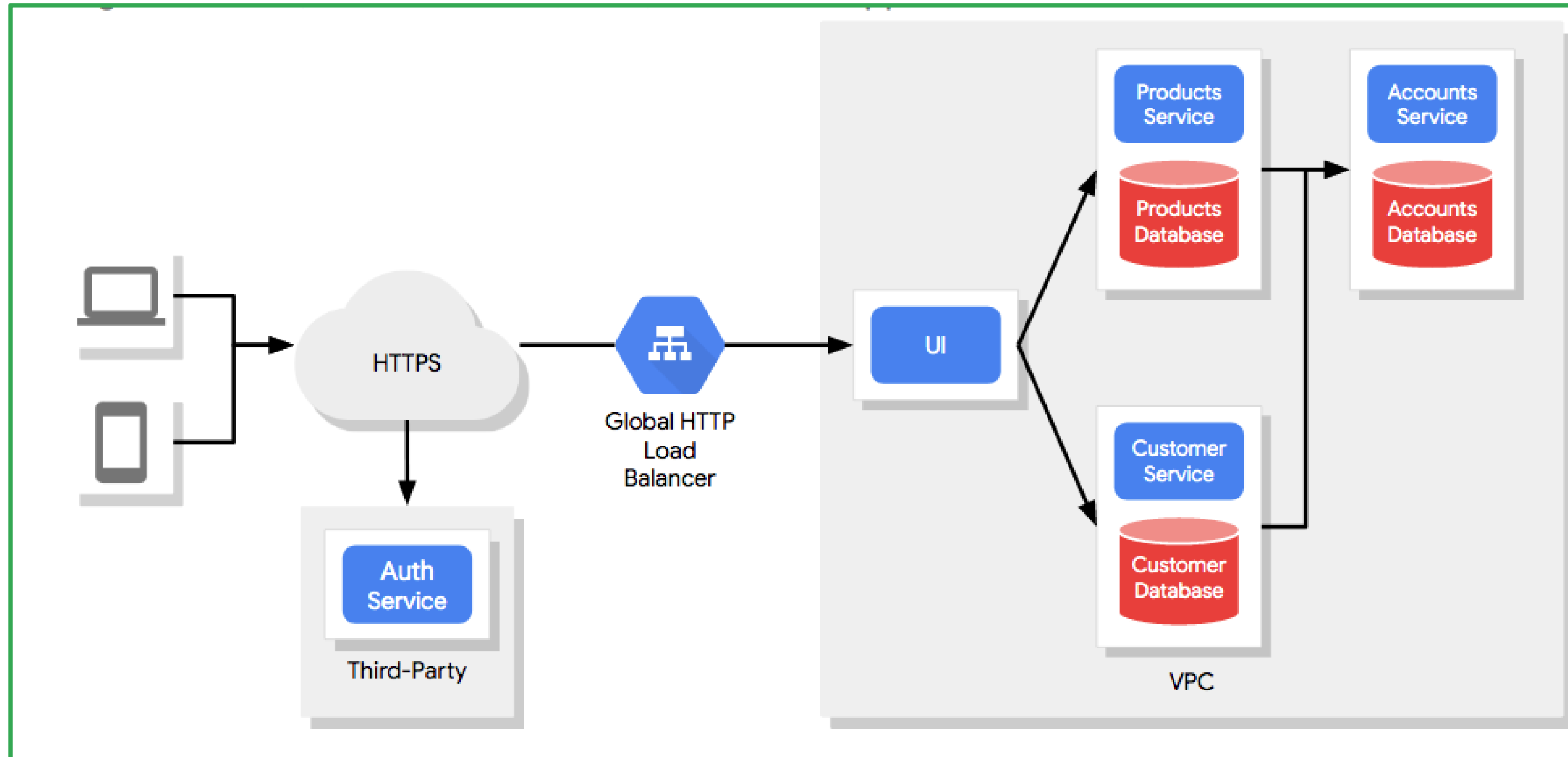**$96 billion**
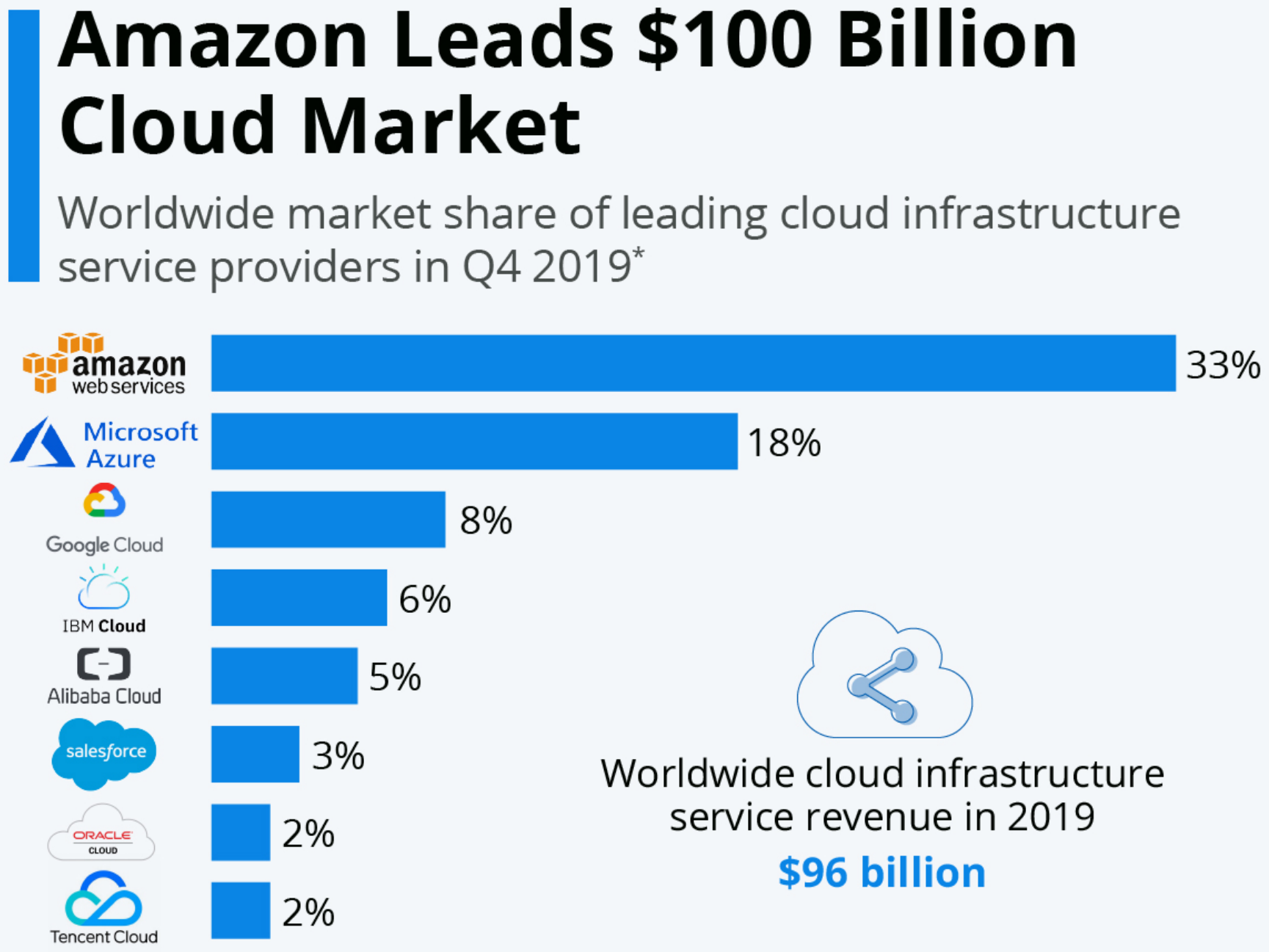
* includes platform as a service (PaaS) and infrastructure as a service (IaaS) as well as hosted private cloud services
Source: Synergy Research Group

statista

What makes cloud computing optimal for working with healthcare data?

Representative examples are from GCP

# Pricing for cloud services can be estimated using architecture and projected load

- No sunk costs; operational expenses can be estimated by knowledgeable cloud architects.
- Discounts for preemptible virtual machines.
- Third-party brokers can cheaply run large jobs on platforms like AWS.

Privacy: HIPAA aligned GCP architecture

- Health Insurance Portability and Accountability Act of 1996 (HIPAA) governs the privacy of patient health information.

  - Applies to health plans and most healthcare providers.

- Data breaches are investigated; may result in penalties.

- HIPAA is currently suspended by the administration to encourage telehealth amidst the COVID-19 crisis.
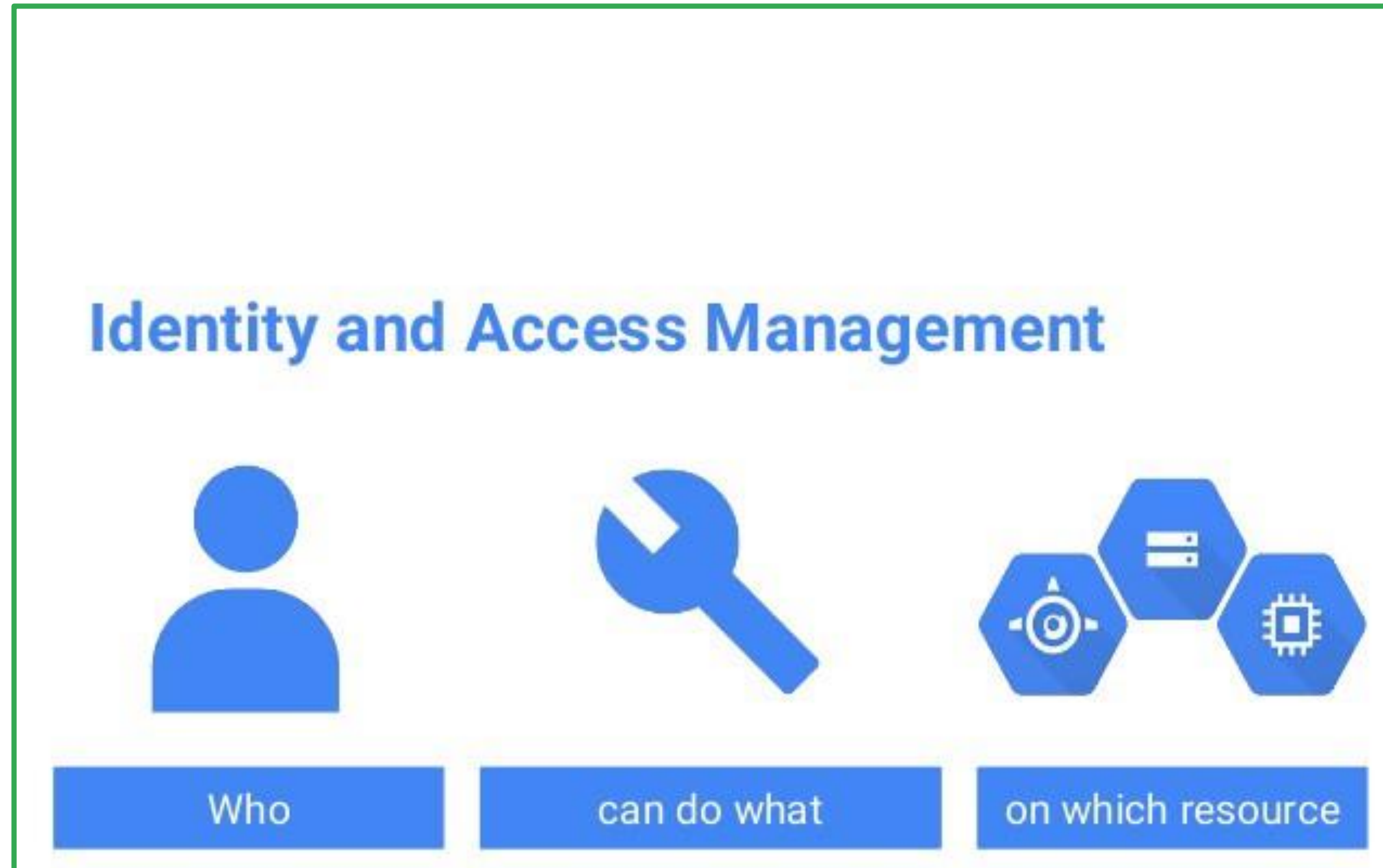
HIPAA aligned GCP architecture
Key Concept: A project is a wrapper for billing and resources (storage, virtual machines, databases…)
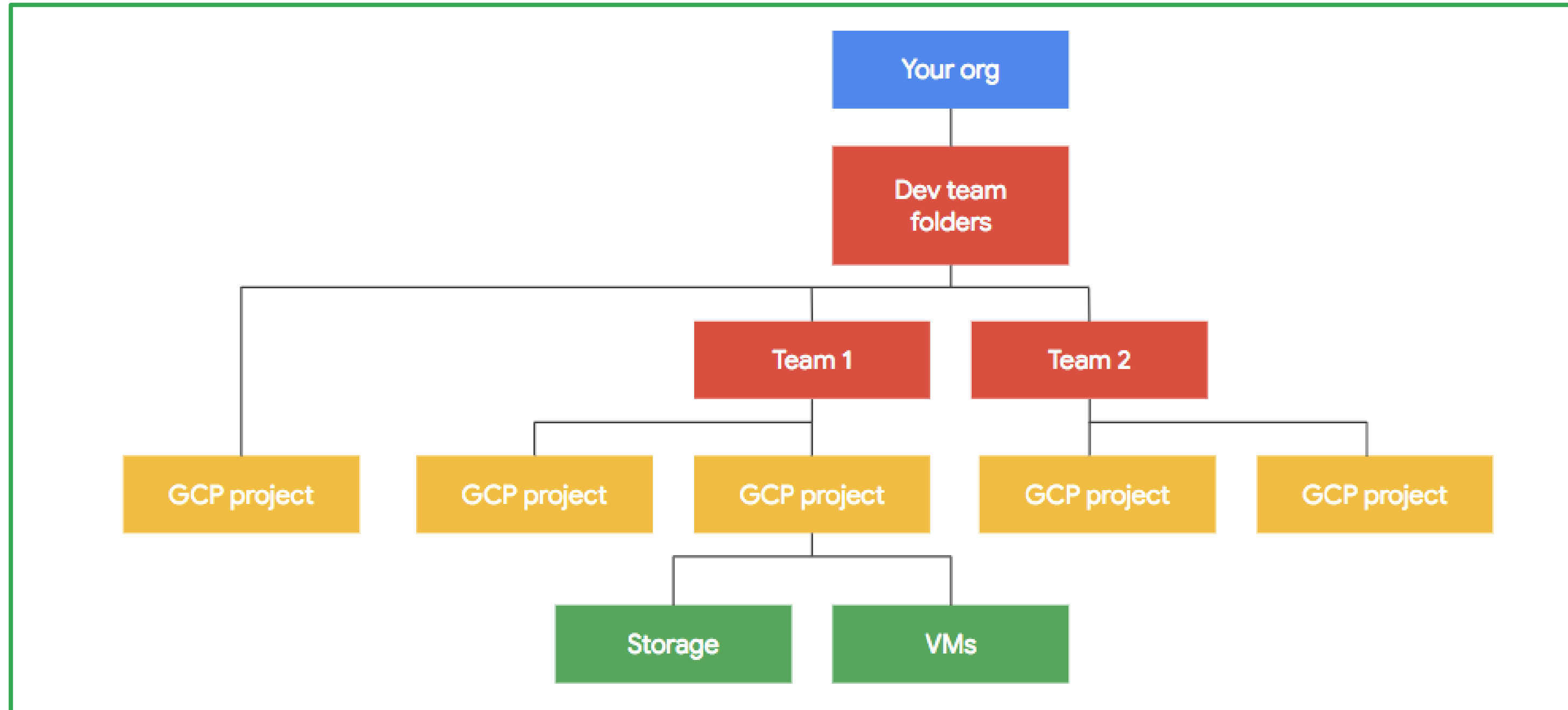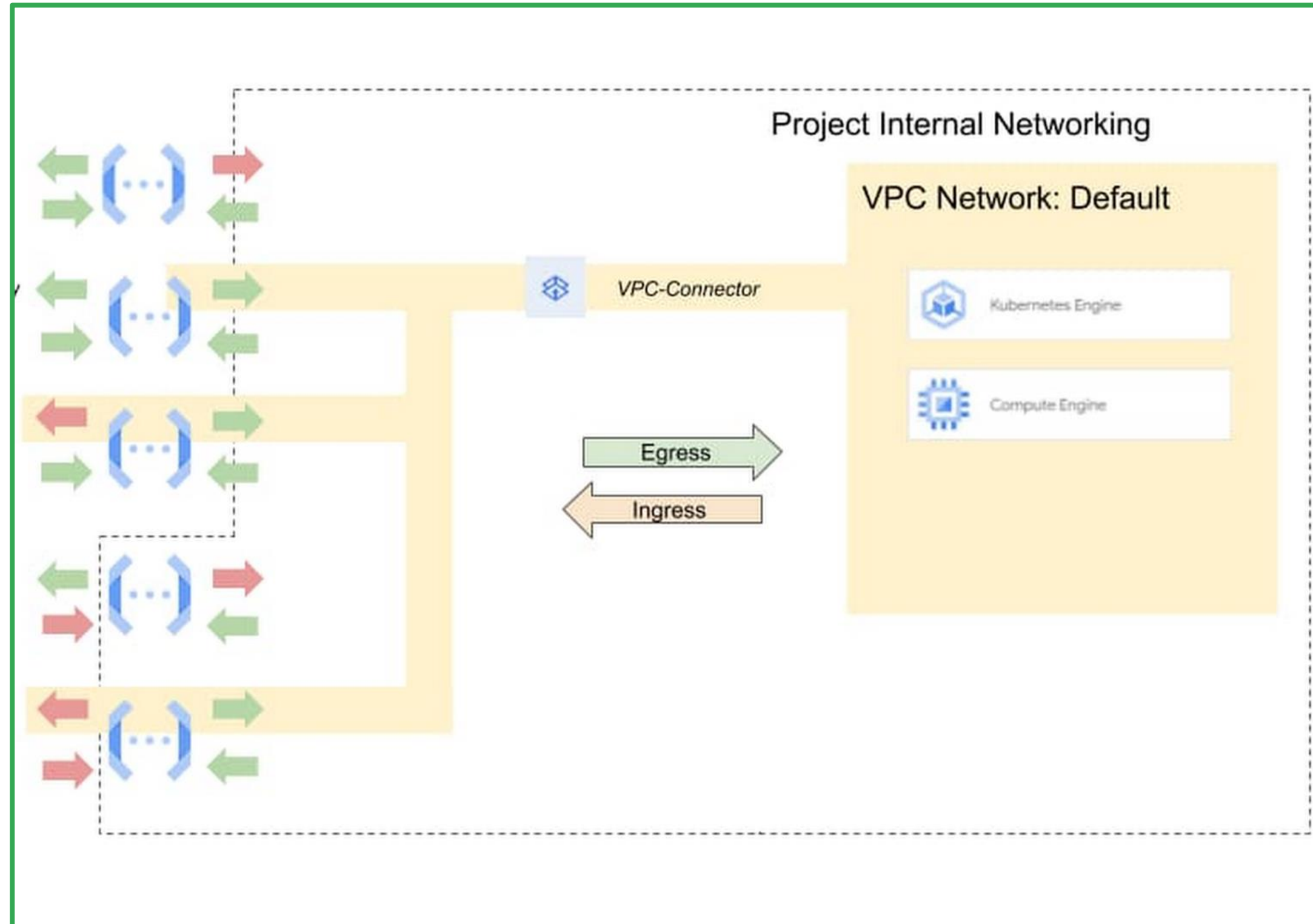
HIPAA aligned GCP architecture
Key Concept: Identity and Access Management (IAM)

Identity and Access Management

Who | can do what | on which resource

- **Service accounts** provide access for a service or an app (to access a database, for example).

HIPAA aligned GCP architecture
Key Concept: Virtual Privacy Cloud (VPC)

- Connects to an outside 'peer' network using a Virtual Privacy Network.

HIPAA aligned GCP architecture: Key components

| Key Resource	Description
Project	Wrapper for billing and resources.
Identity and access management	Assign users to groups with levels of resource access.
Service accounts	Access for a service or an app.
Enterprise connectivity	Several options to match customer criteria for speed.
Virtual Private Cloud network	Global; Each project has at least one with internal IP addresses.
Audit logging	Admin activity logs, data access.
Security monitoring and alerting policies	Alerts for unexpected access, access and storage permissions change, database update

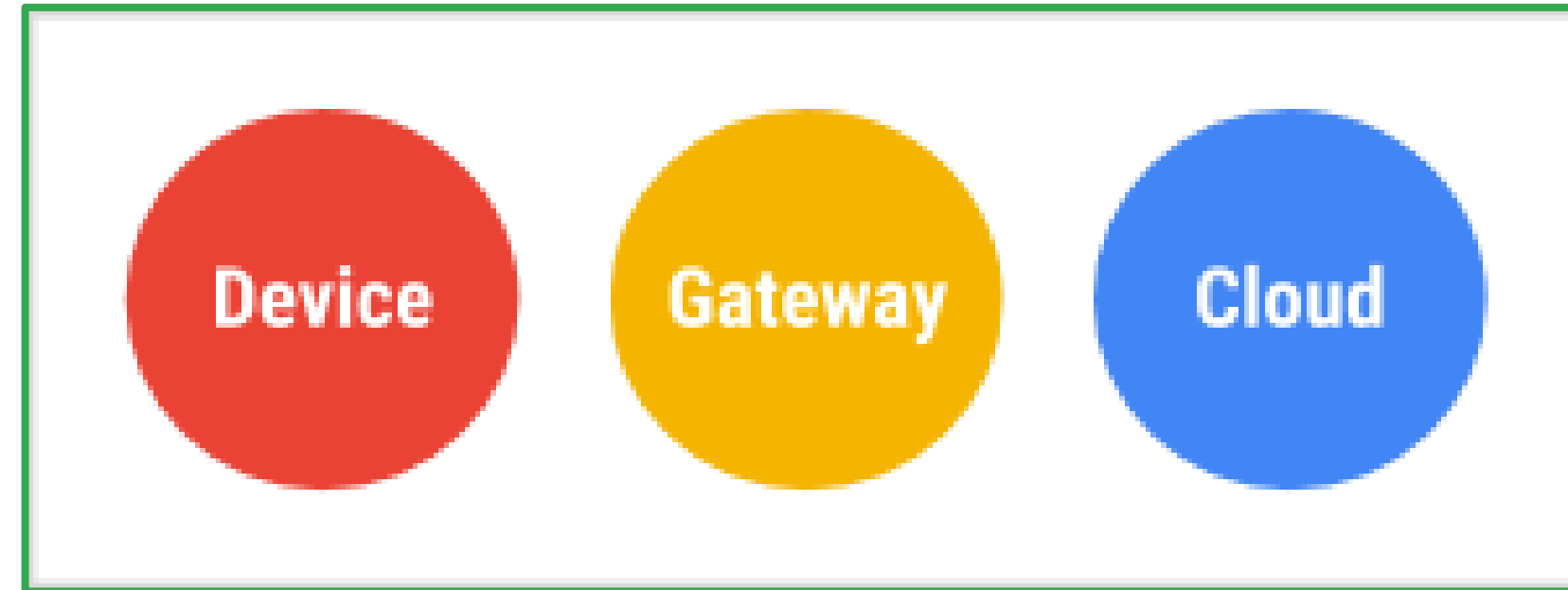# HIPAA-aligned GCP architecture: Implementation
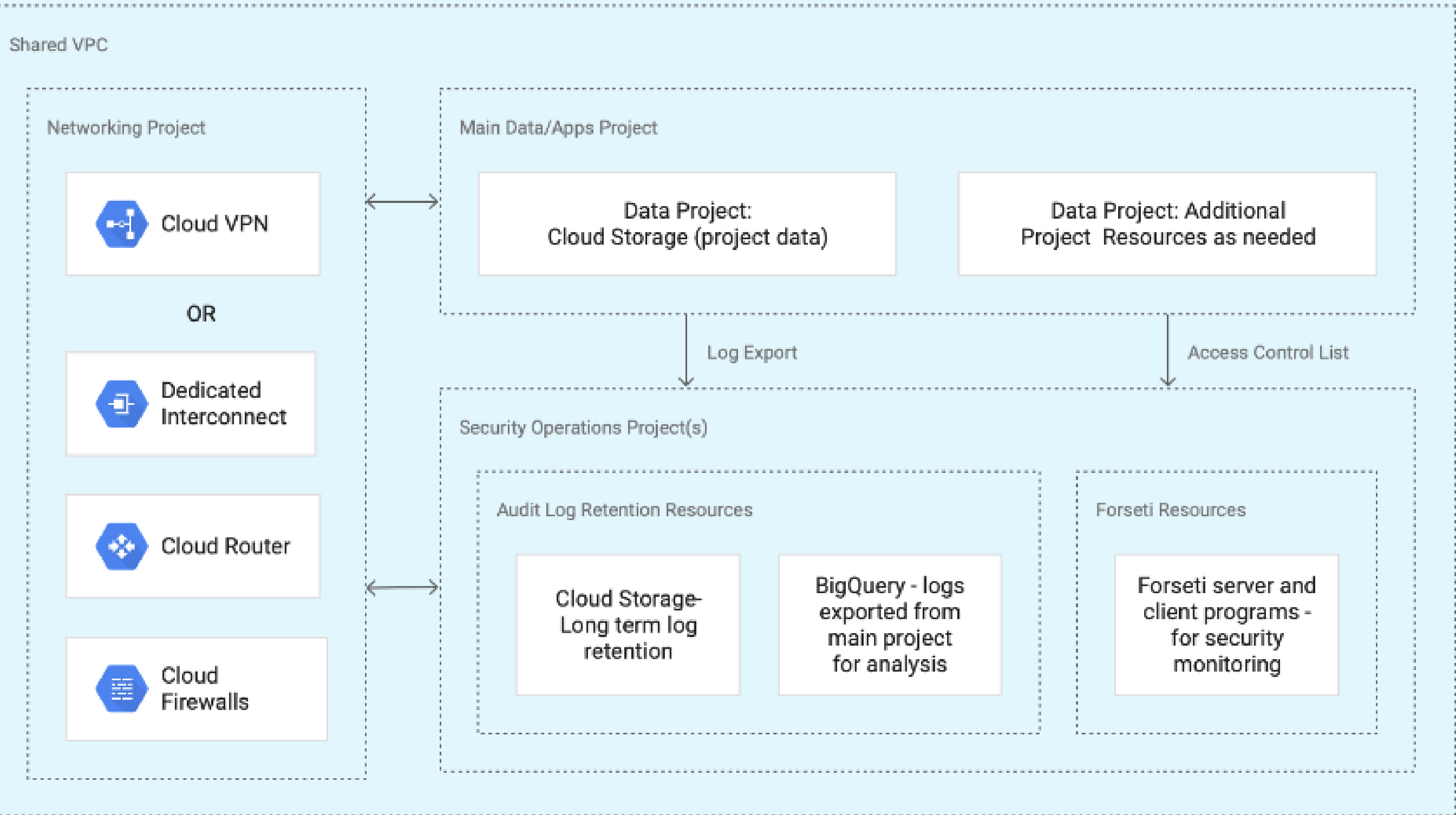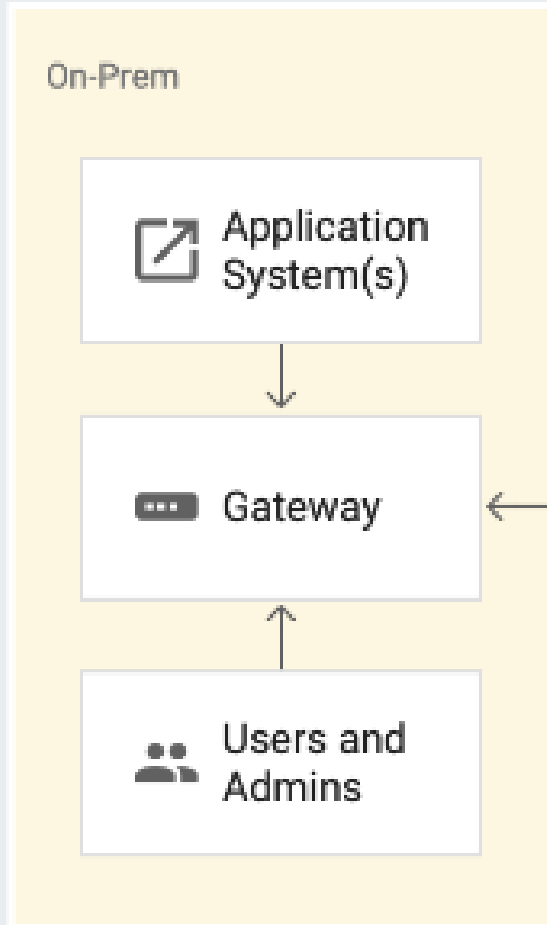
Case study: Cloud Internet of Things (IoT)
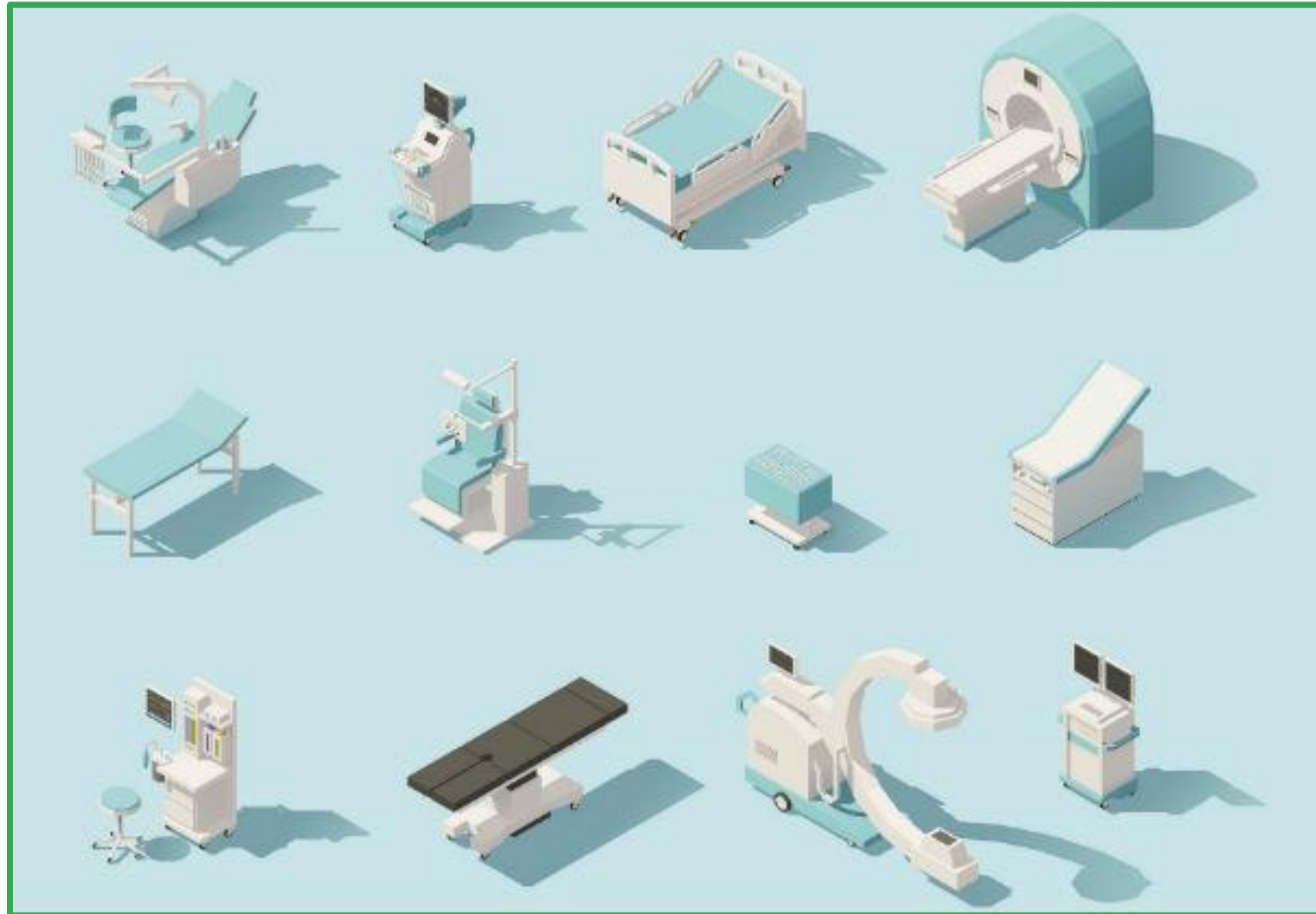
- Cloud solutions address unmet needs in connected medical devices:
  - Data integration with patient EHRs.
  - Alarm management.
  - Clinical surveillance.
  - Remote monitoring.
  - High-fidelity databases for clinical research and simulation.
    - https://www.healthcareitnews.com/news/tech-optimization-medical-device-and-iot-operating-secrets
    - https://hitinfrastructure.com/news/network-connectivity-storage-challenge-healthcare-iot-push

Top level view of IoT

- Device: Hardware and software that directly interact with the world.
  - Telemetry (via sensors), device metadata, and device state.
- Gateway provides connection to the internet.
  - Receiving commands, providing data.
- Cloud-based apps process device data and can combine it with other datasets.

Cloud IoT schema for device data management

Sensors

Control

Data

Ingestion

Cloud Dataflow
for streaming and batch analytics

Cloud Pub/Sub
for ingest connection and management

Cloud IoT Core
for device connection and management

BigQuery
for data warehouse and fast querying

Cloud ML Engine
for train, deploy, and run ML model

Other Cloud Services

Visualization
Time series dashboard
Archival storage
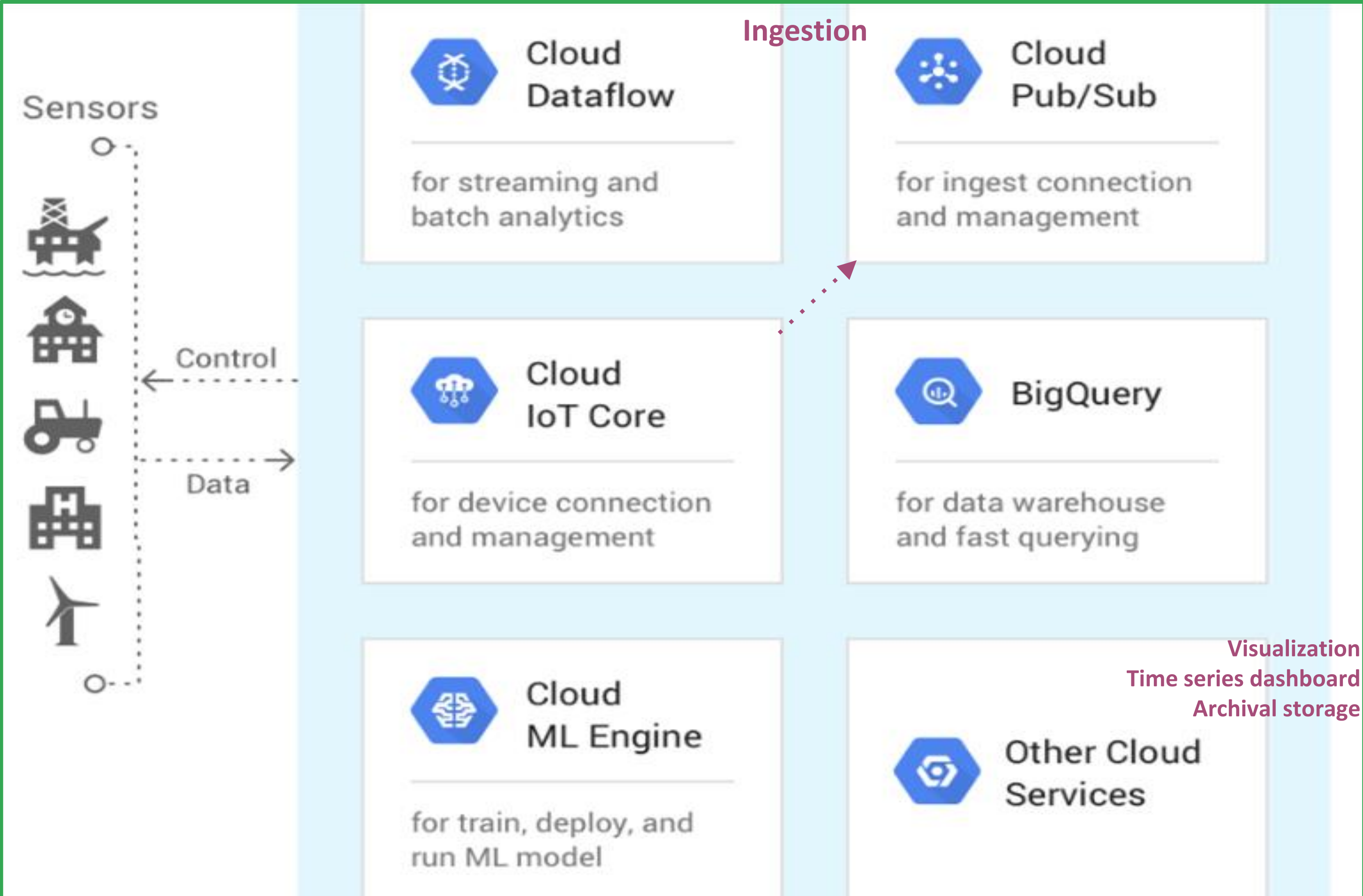
Cloud Computing -- Synopsis

Large cloud platforms provide an array of fully-managed services with a global footprint

Google Cloud Platform Regions
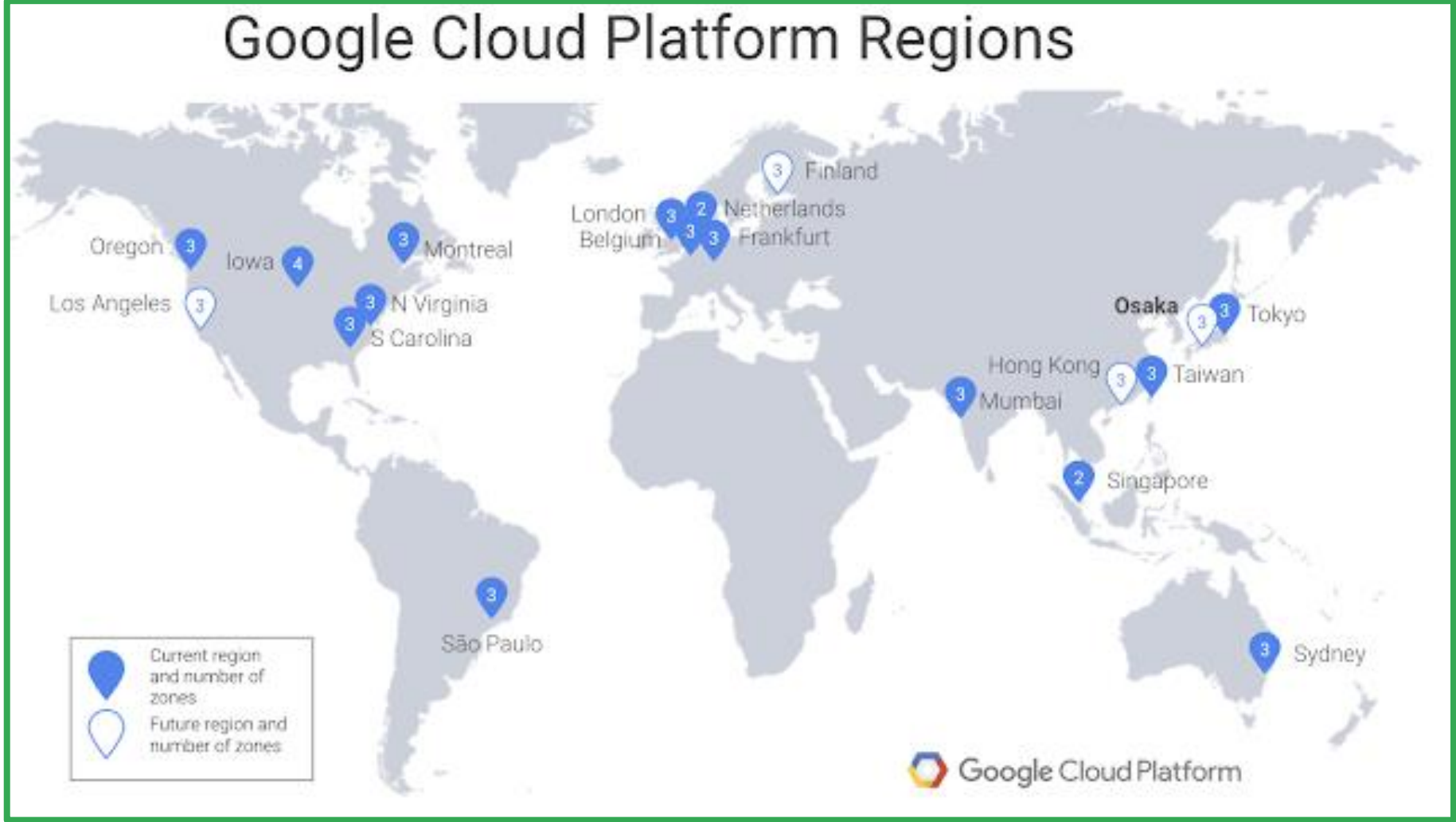
Compute	Compute Engine	Kubernetes Engine	App Engine	Cloud Functions	
Management	Cloud Console	Stackdriver	Trace	Logging	Debugger	Monitoring
Networking	Cloud Load Balancing	Cloud CDN	Cloud DNS	Firewall Rules	Cloud Interconnect	Cloud VPN
Storage & Databases	Cloud Bigtable	Cloud Datastore	Cloud Spanner	Cloud SQL	Cloud Storage	
Big Data	BigQuery	Cloud Dataflow	Cloud Dataprep	Cloud Dataproc	Cloud IoT Core	Cloud Pub/Sub
Identity & Security	Cloud IAM	Cloud Endpoints	VPC	Identity Aware Proxy	KMS	Data Loss Prevention
Machine Learning	Cloud ML	Natural Language API	Cloud Speech API	Cloud Vision API	Cloud Translate API	

Competing services offerings encourage multi-cloud architectures

Product	aws	Microsoft Azure	Google Cloud Platform
Virtual Service	Instances	VMs	VM Instances
Platform-as-a-Service	Elastic Beanstalk	Cloud Services	App Engine
Serverless Computing	Lambda	Azure Functions	Cloud Functions
Docker Management	ECS	Container Service	Container Engine
Kubernetes Management	EKS	Kubernetes Service	Kubernetes Engine
Object Storage	S3	Block Blob	Cloud Storage
Archive Storage	Glacier	Archive Storage	Coldline
File Storage	EFS	Azure Files	ZFS / Avere
Global Content Delivery	CloudFront	Delivery Network	Cloud CDN
Managed DWH	Redshift	SQL Warehouse	Big Query

Conclusions

Trends for Cloud-Based Healthcare Data Systems

- Cloud computing fully supports large-scale observational studies and data-driven simulations, with strong near-term impact on regulatory pathways and healthcare delivery.

- Cloud platforms are investing significantly in their packaged solutions for healthcare, pharma/biotech and bioinformatics.

- Current waiver of HIPAA enforcement is spurring more interest in cloud computing.

- Open-source managed software packages have reduced the burden of coding.
  - Instead, cloud computing requires platform architects and data pipeline engineers with significant opportunities for consultants.