Welcome to the
22nd PIA REGULATORY CONFERENCE

AI
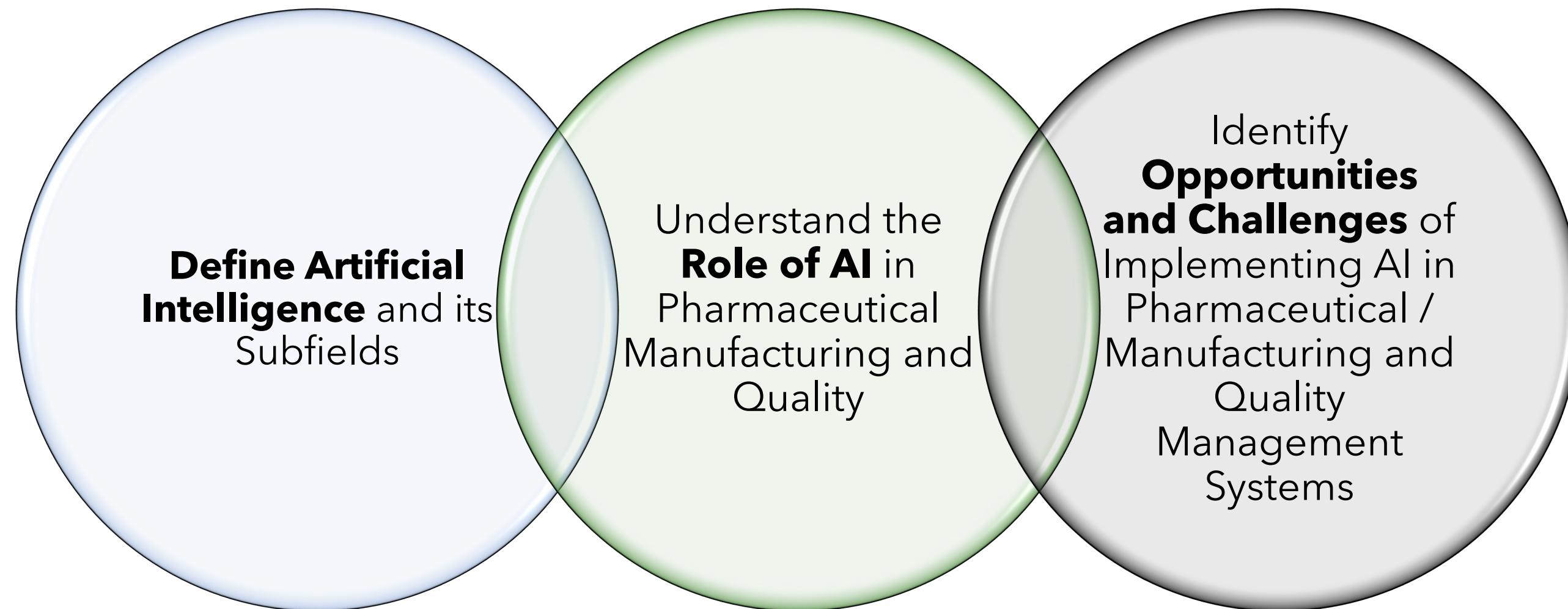THE FUTURE IS NOW
AI IN QUALITY

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Understanding Artificial Intelligence

Understanding Artificial Intelligence

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Objectives

Define Artificial Intelligence and its Subfields

Understand the **Role of AI** in Pharmaceutical Manufacturing and Quality

Identify **Opportunities and Challenges** of Implementing AI in Pharmaceutical / Manufacturing and Quality Management Systems
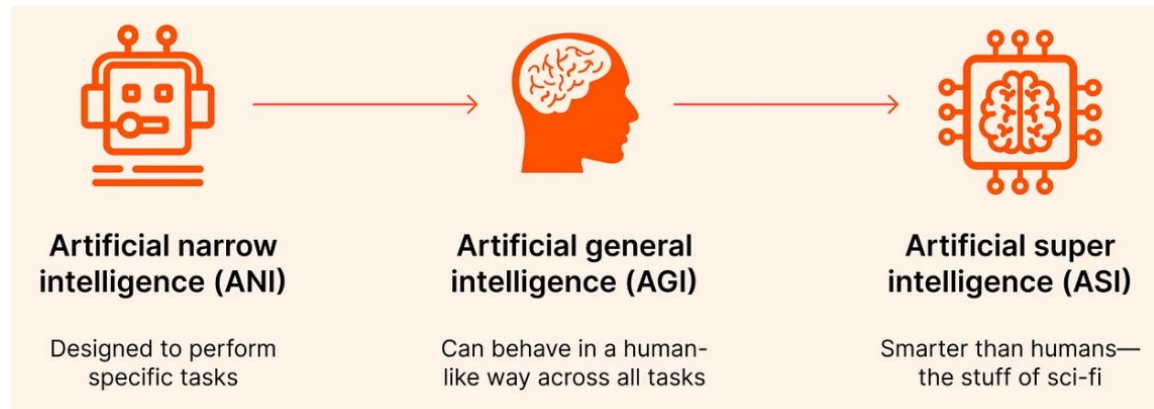
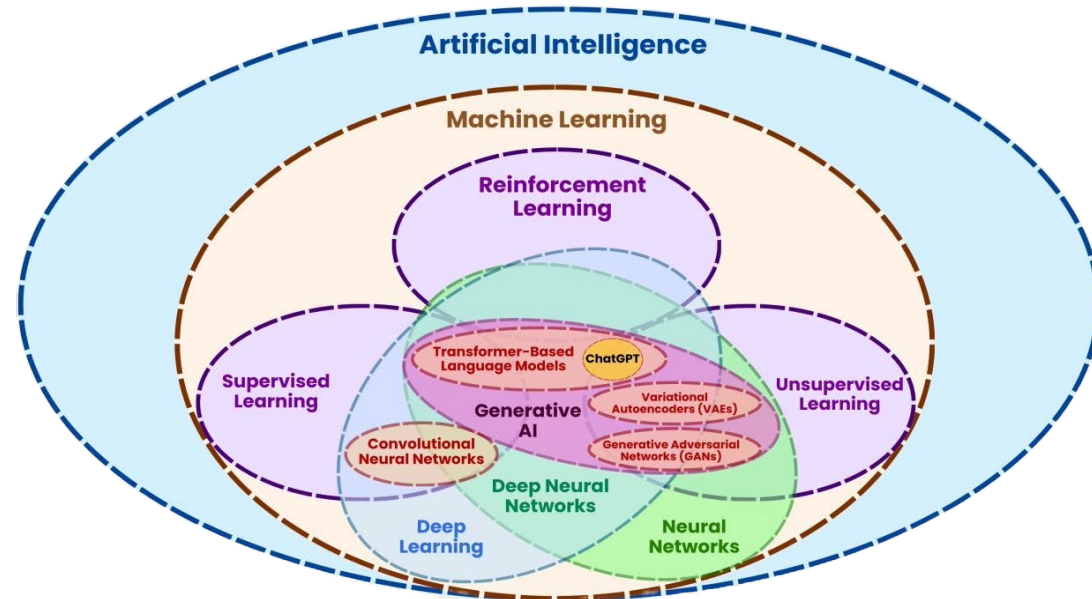# Types, Components, and Subfields of AI
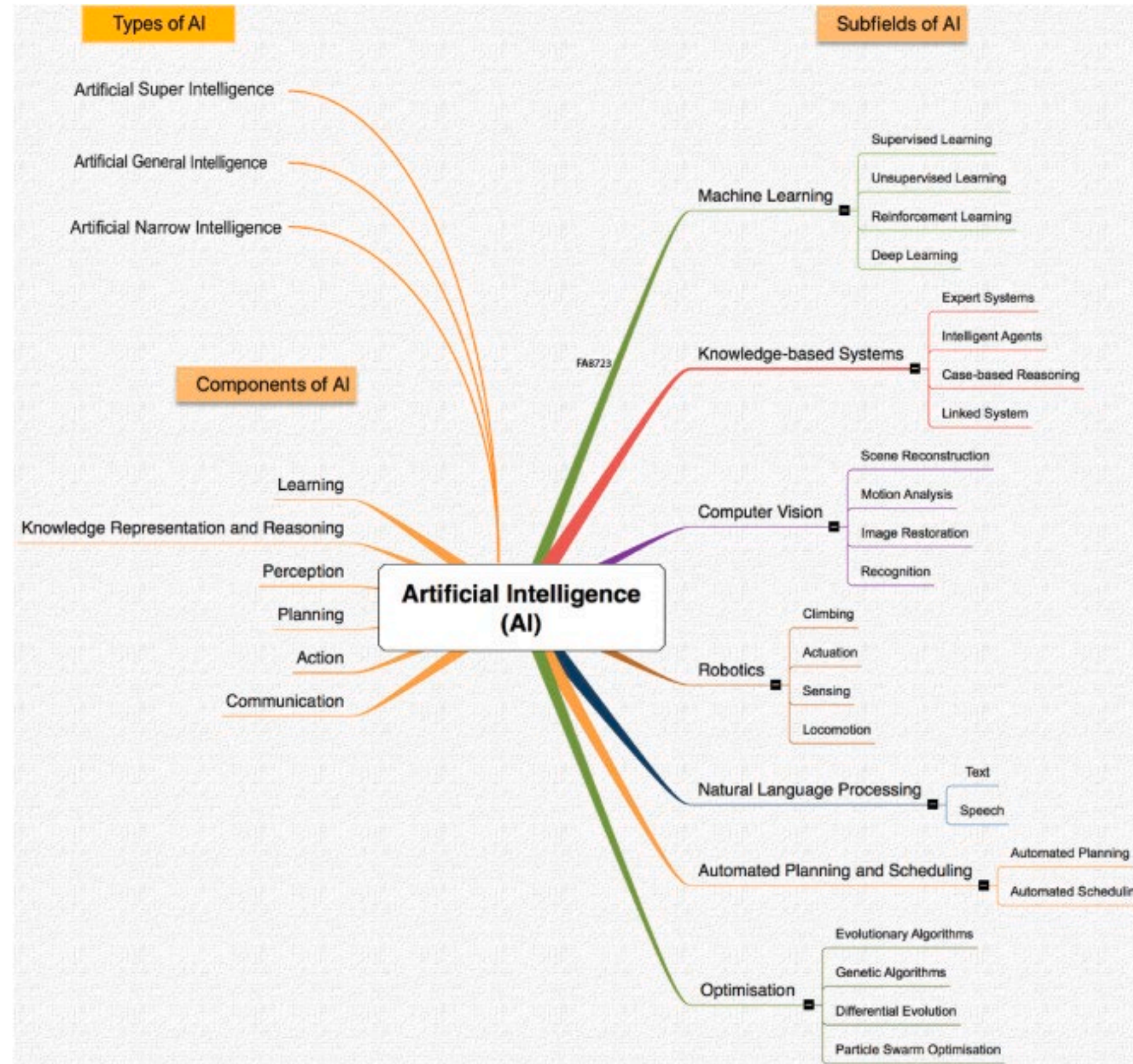
Artificial Intelligence

A branch of computer science, statistics, and engineering that uses algorithms or models that exhibit behaviors such as learning, making decisions, and making predictions.

Machine Learning

Definition

Machine learning involves computer systems that can **learn and make decisions by themselves** by **recognizing patterns in data**, without being explicitly programmed on what to do.

Possible Applications

- Predicting equipment maintenance
- Risk Management
- Investigations
- Audit Preparedness
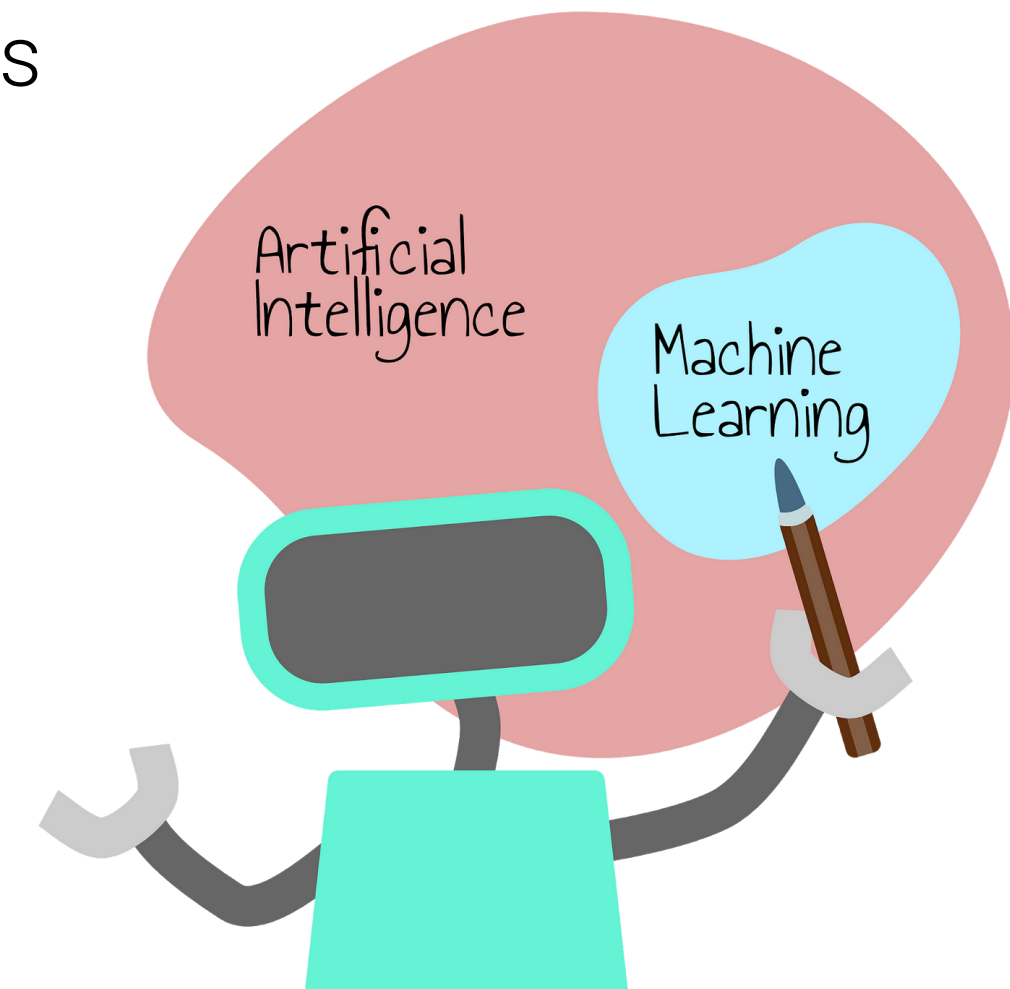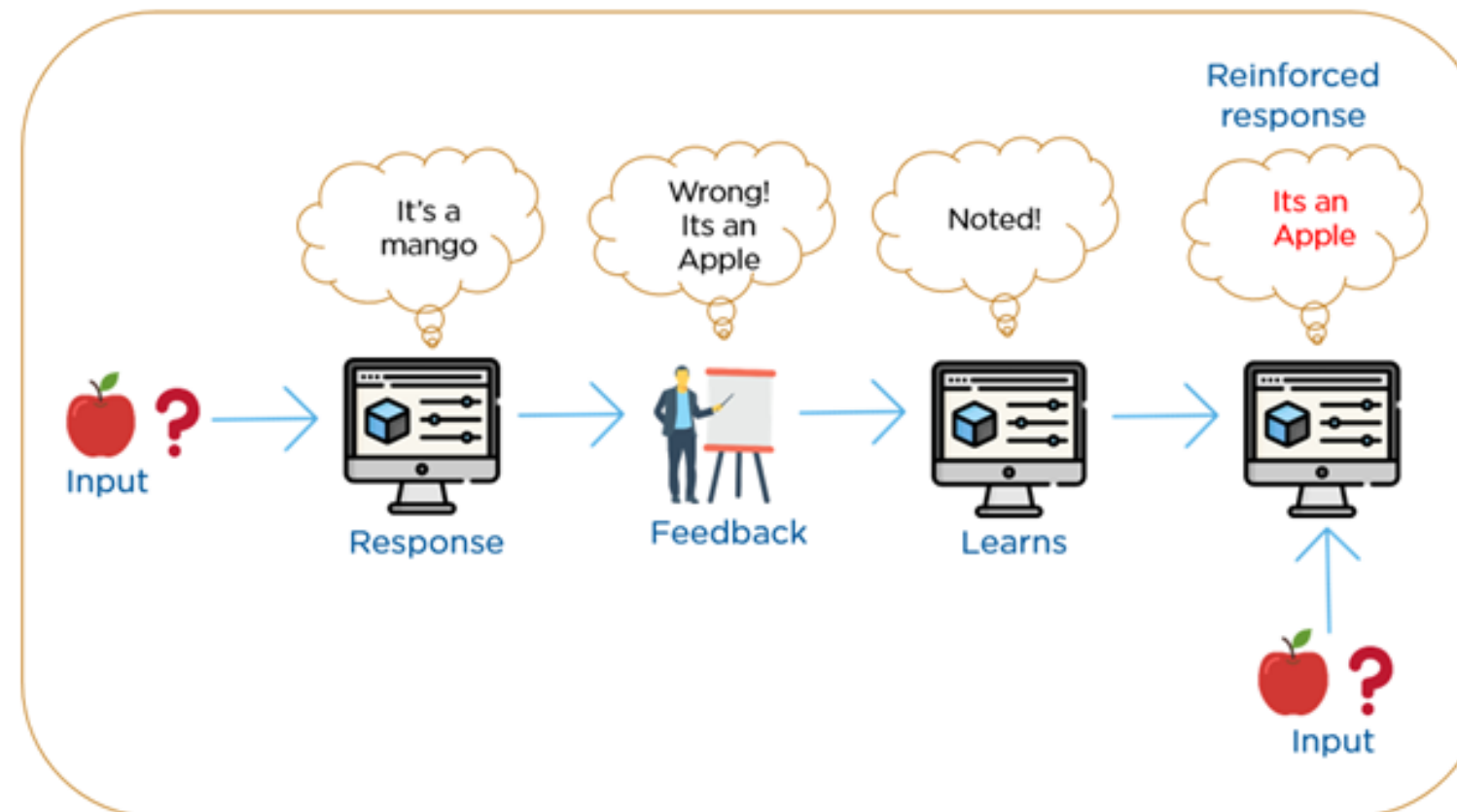
Deep Learning

Definition

A specialized branch of machine learning that uses **neural networks** with many layers to **analyze complex data.**

Applications

- Drug discovery / Identify potential compounds

- Enhance quality control through advanced image analysis

- Precise Investigations
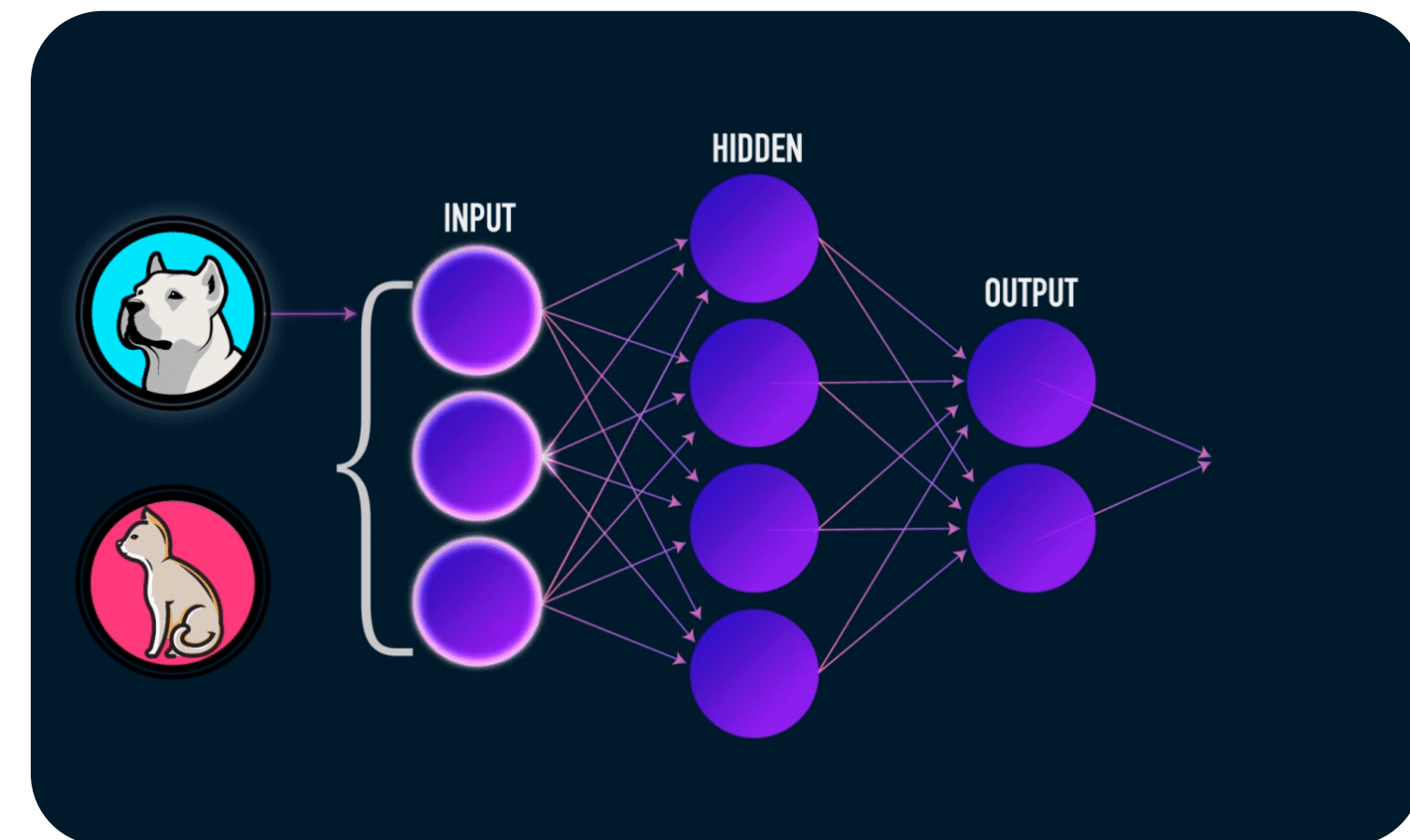
Natural Language Processing

Definition

A field of AI focusing on the **interaction between computers and human language**, enabling machines to understand, interpret, and generate human language.

Possible Applications

- **Automated Creation:** Enhances the drafting process of SOPs and regulatory documents, ensuring accuracy and compliance with FDA standards.
- **Information Extraction:** Pulls key data automatically from existing documents.
- **Content Categorization:** Sort and file documents based on their content.
- **Document Organization:** Arrange all documents for easy access and reference.
- **Continuous Updating:** Keeps documents current by integrating new information as it becomes available.
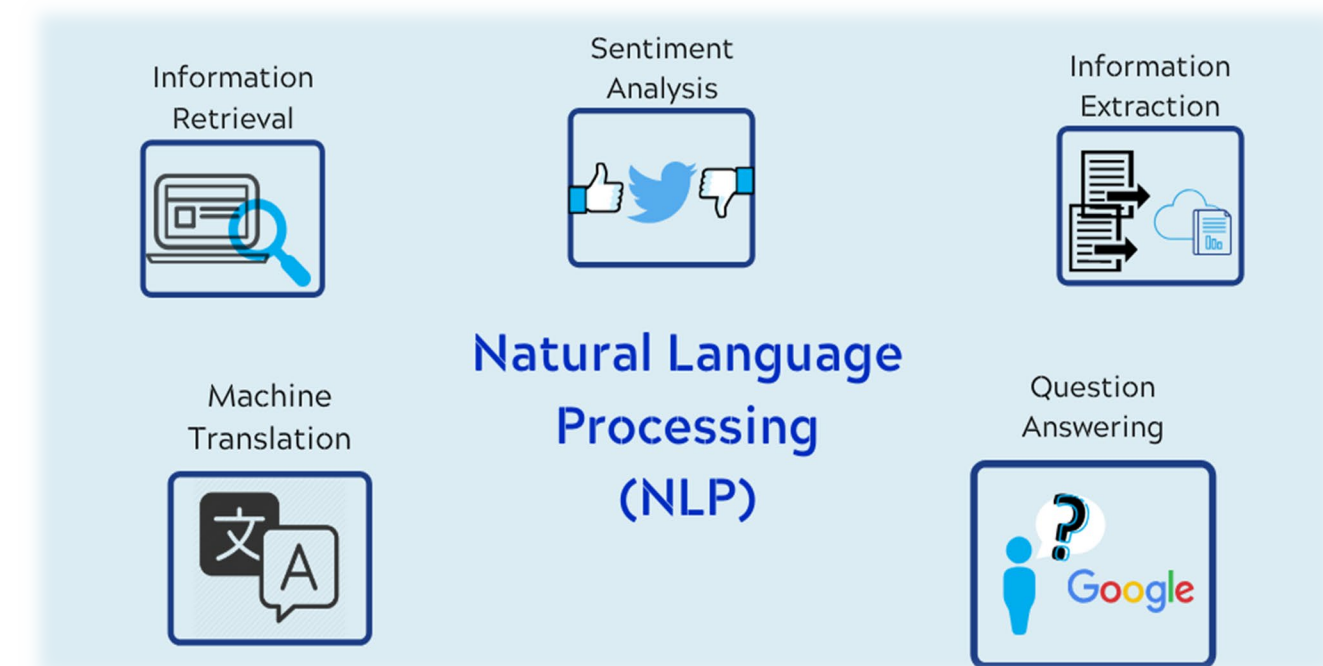
Computer Vision

- Definition
  - A technology that allows computers to interpret and make decisions based on **visual input** from the physical world.

- Possible Applications
  - Defects or contamination inspection
  - Packaging Quality Assurance
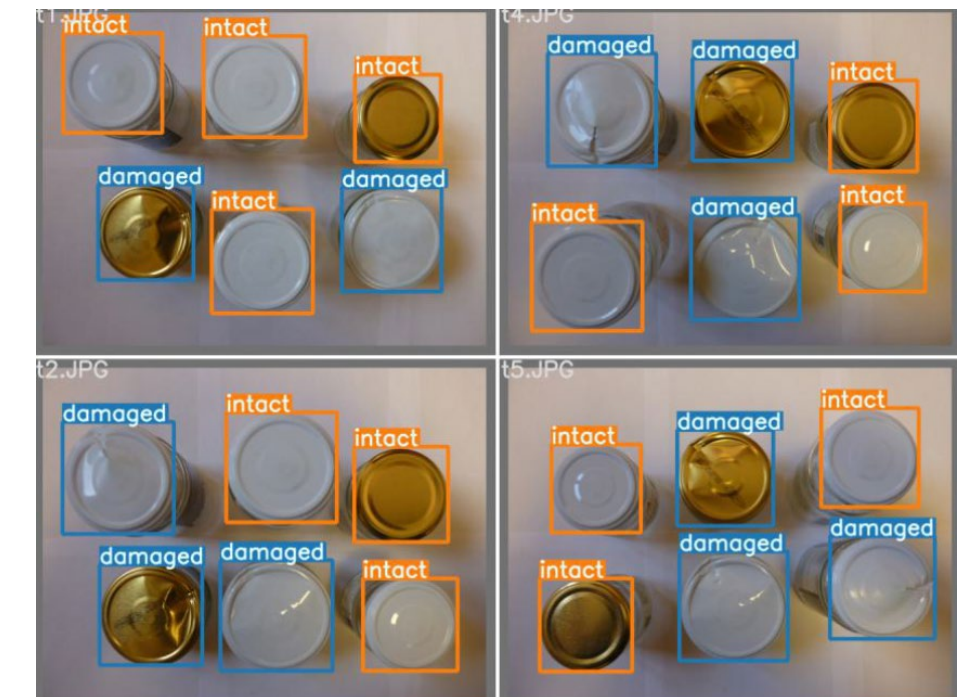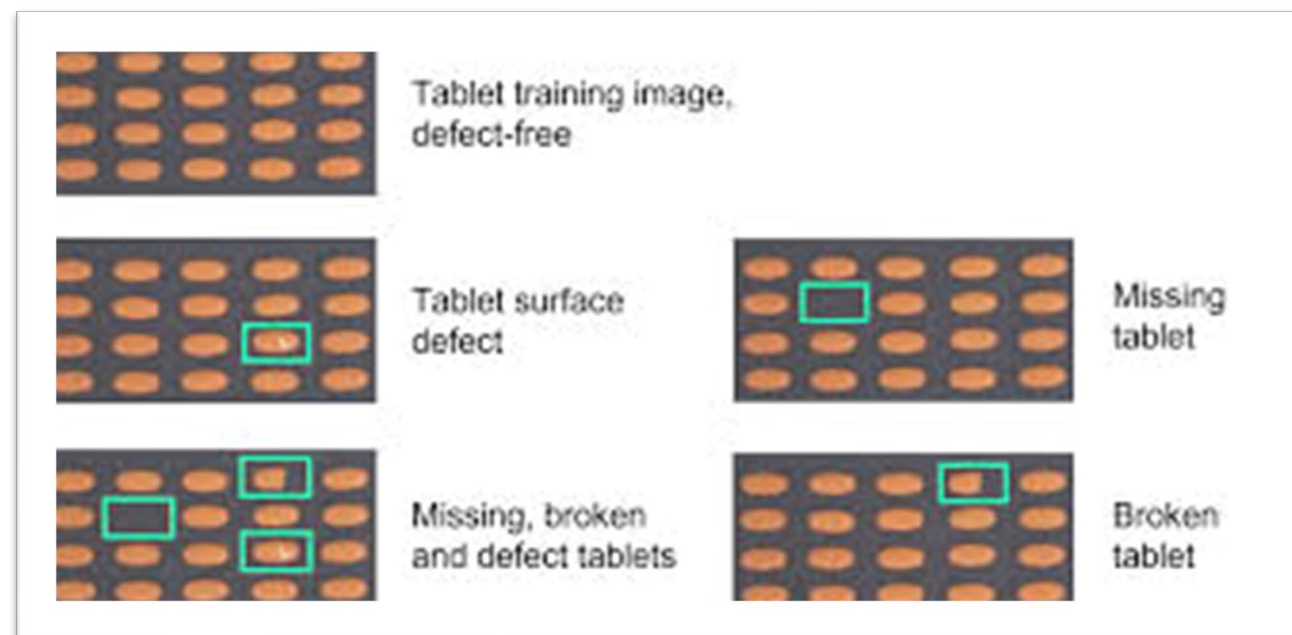
Latest AI Technology Trends

Generative Models

Algorithms designed to generate new data based on the patterns it learns from input data, such as images and text.

Uses a combination of neural networks, including GANs, RNNs, VAEs, Deep Reinforcement Learning, Transformer Models, and others, to simulate and innovate within data-driven environments.

"pink toy horse on the beach"

Applications:
- Drug Discovery, Design and Speed to Market
  - **Accelerated Identification:** Use generative models to quickly predict new drug molecules.
  - **Enhanced Precision:** Improve drug-target interaction predictions to cut screening time and cost.
- Personalized Medicine
  - **Customized Therapies:** Predict individual responses for tailored treatments.
  - **Gene Therapy:** Design targeted therapies for genetic profiles.
- Manufacturing Optimization
  - **Process Simulation:** Optimize processes for better quality and yield.
  - **Material Innovation:** Create new formulations for improved stability and delivery.

Reinforcement Learning

A branch of machine learning focused on how agents **take actions in an environment** to maximize cumulative reward.

Applications:
- Optimize production processes
- Supply chain management
- Robotic arms for precise packaging of delicate vials and ampoules
  - Precision Handling: Train robotic arms to handle and package fragile vials
  - Adaptive Movements: Learn to optimize movements based on real-time grip pressure, speed, and placement accuracy feedback.
  - Real-Time Adjustments: Dynamically adjusts the grip force and movement trajectories to handle different packaging scenarios.
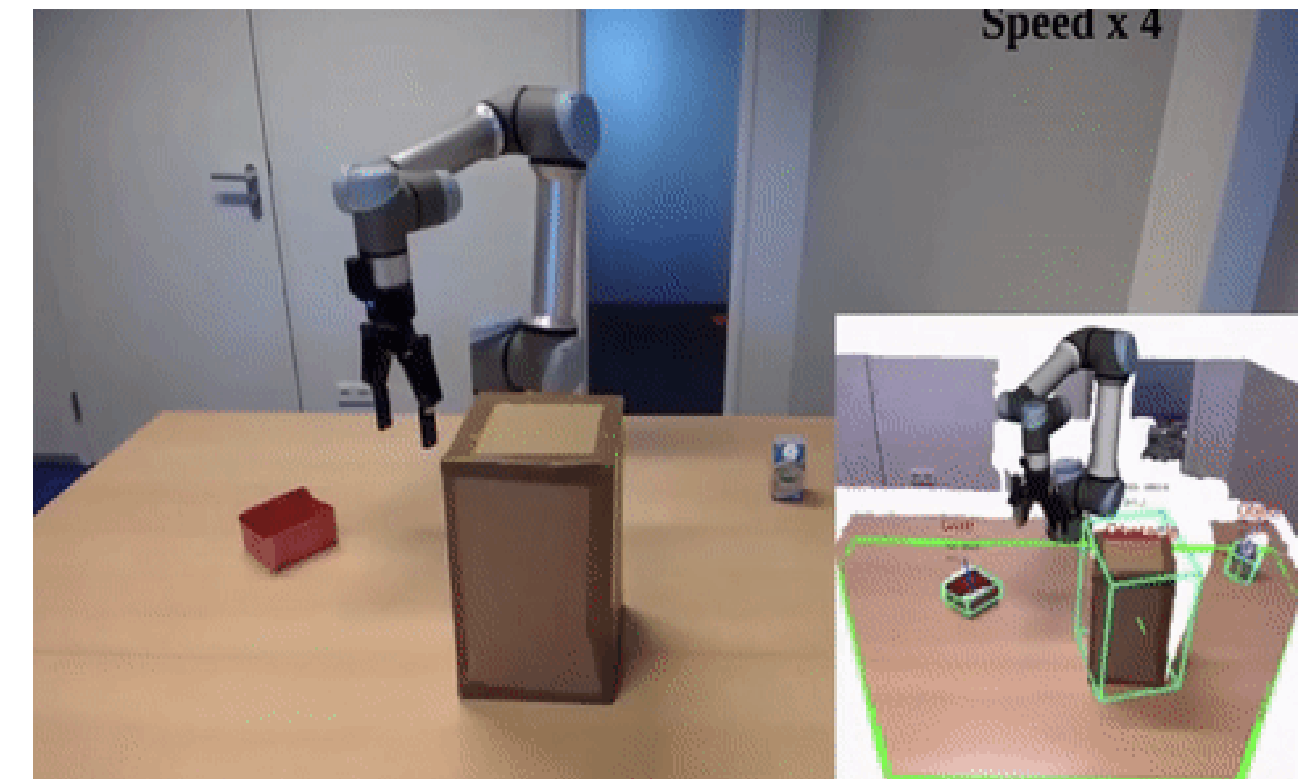
Federated Learning

Collaborative machine learning approach that allows multiple organizations to train AI models using shared knowledge without sharing their proprietary information.
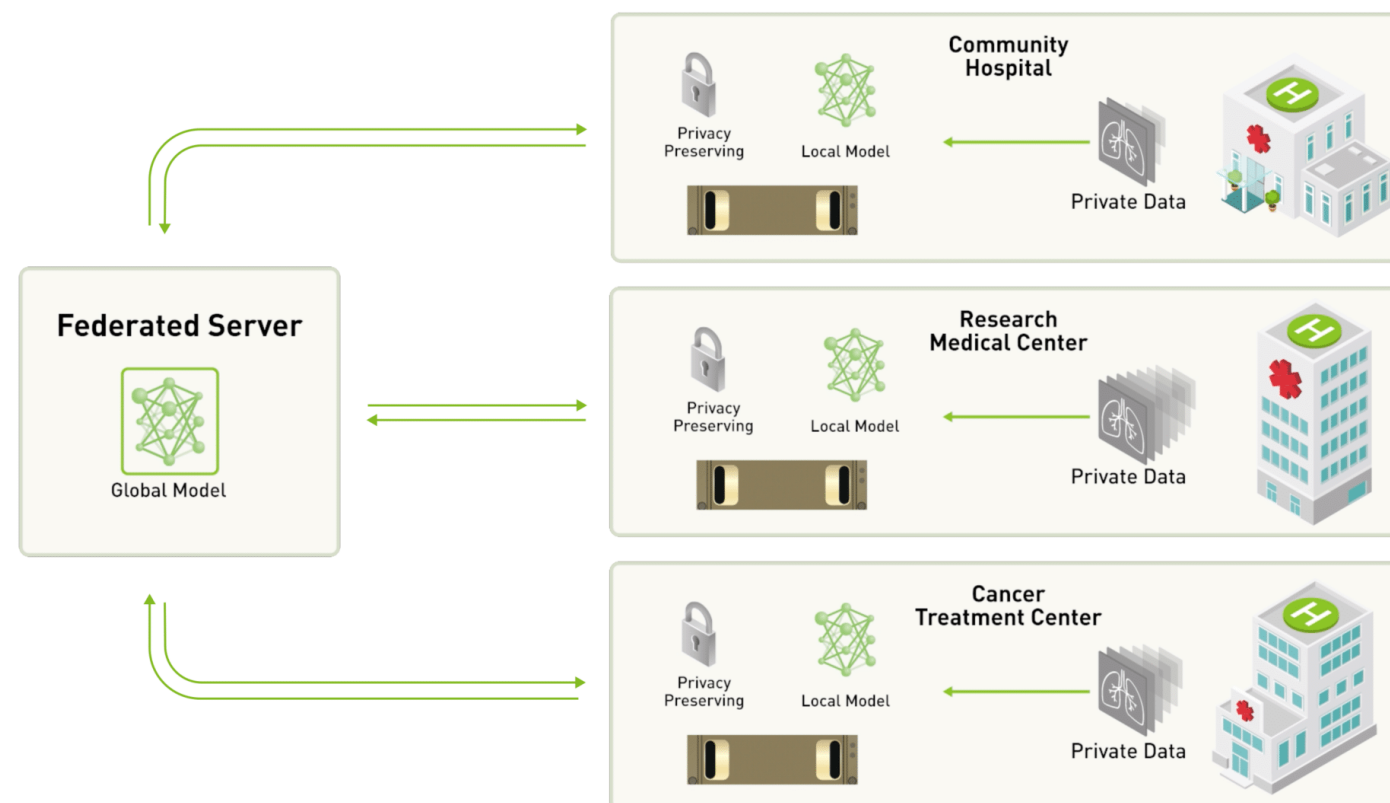
Enhanced Data Security:
- Protect sensitive information while benefiting from diverse data sources for robust model training.

Enables Knowledge Management.

Application:
- ✓ Improve predictive models for patient outcomes without compromising patient data privacy.
  - ➢ Cell & gene therapy
  - ➢ Personalized medicine

Explainable AI (XAI)

Set of techniques and methods that make the decision-making processes of AI models **transparent** and **understandable**, enabling users to **comprehend and trust** the AI's outputs.

- Why is XAI crucial in Pharma Manufacturing and Quality?
  - Transparency and Trust:
    - **Clear Explanations:** XAI provides clear, understandable explanations for AI decisions, which is essential for **building trust among users and stakeholders** in the pharmaceutical industry.
    - **Enhanced Decision-Making:** By understanding the rationale behind AI outputs, operators and quality assurance teams can make more informed and accurate decisions.
  - Compliance and Accountability:
    - **Regulatory Standards:** XAI provides **detailed justifications for AI systems**, ensuring they meet stringent regulatory standards.
    - **Accountability:** XAI models are **accountable** for their actions, making tracing and validating decisions easier, essential for maintaining compliance and ensuring patient safety.
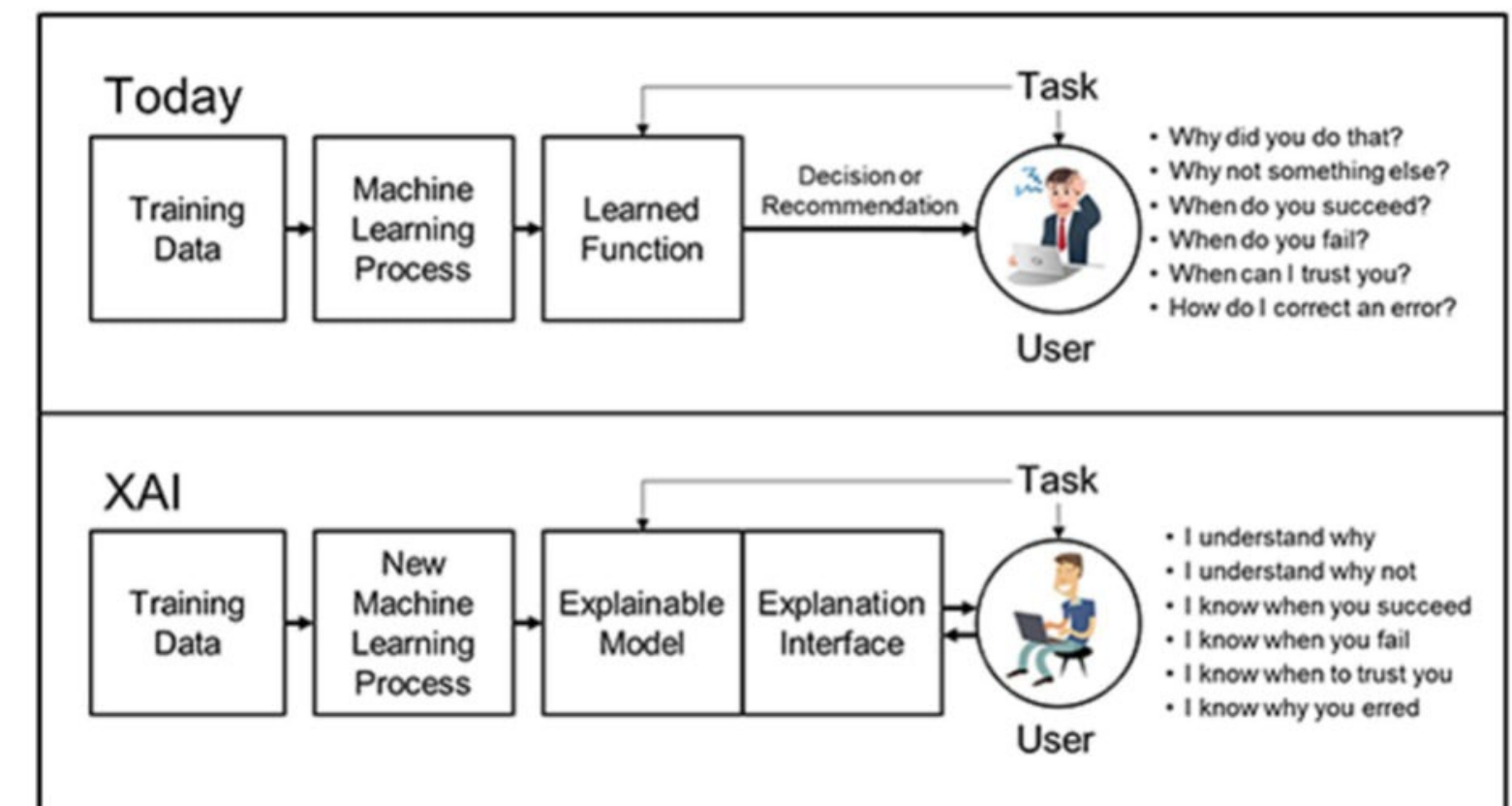
Edge vs Cloud vs Hybrid Computing

Edge AI
- Involves processing data locally on devices at the network's edge, reducing latency and enhancing real-time data processing capabilities.

Cloud AI
- Leverages massive cloud computing resources to perform more complex analyses and store larger datasets than edge devices can handle alone.

Hybrid computing
- Combines edge and cloud computing, utilizing local and remote processing to optimize performance and cost. It processes critical data on the edge for lower latency and leverages cloud resources for scalability. This approach supports real-time analytics and sensitive data handling, providing flexibility and enhanced security for diverse computing needs.
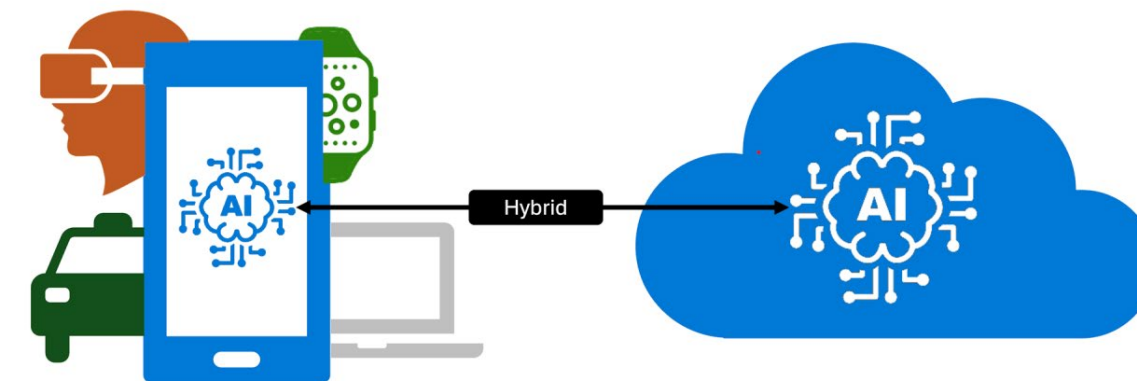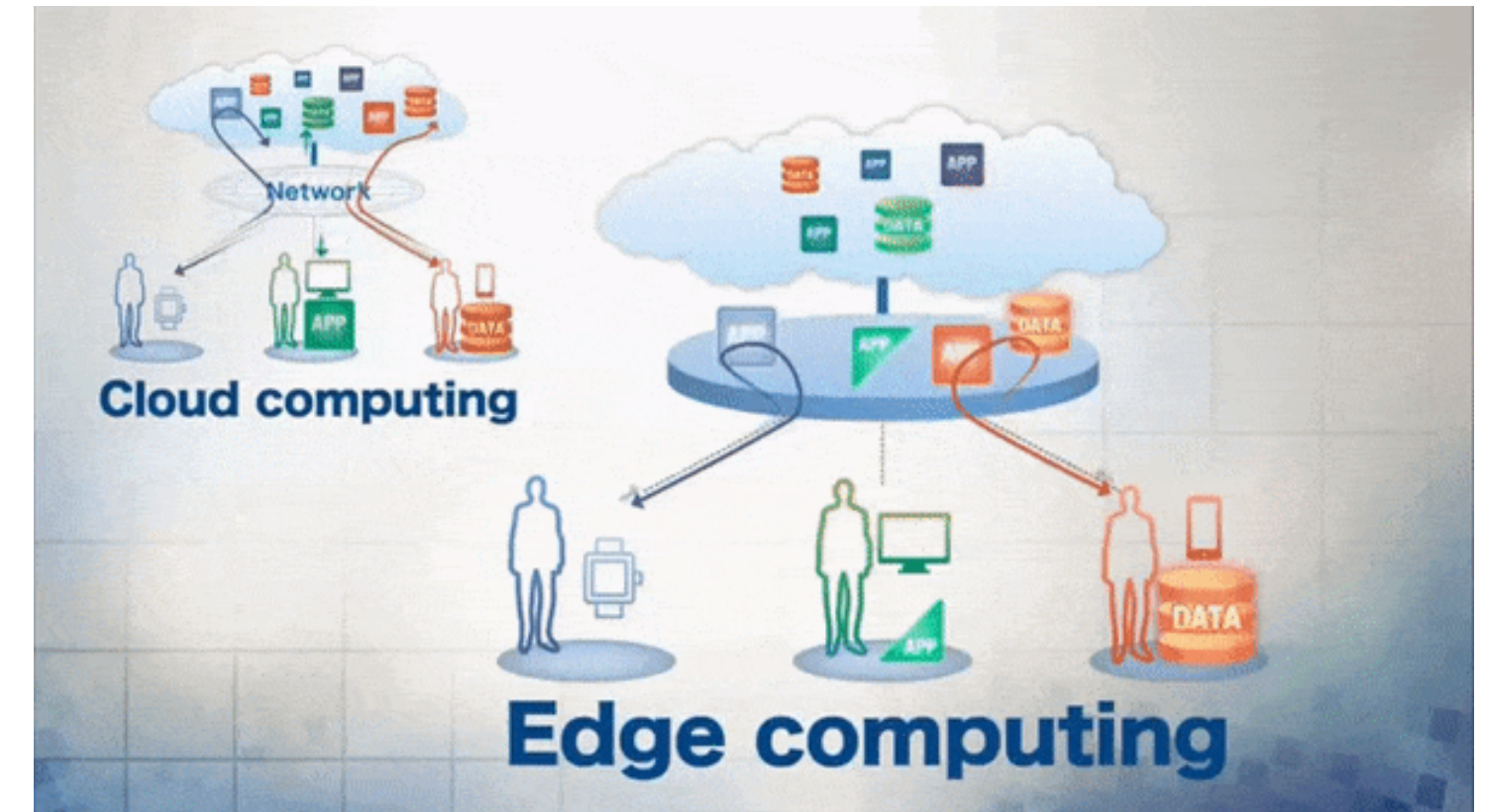
AI for Cybersecurity

Proactive Defense:

- AI systems detect and respond to cyber threats in real time, enhancing security measures.

Predictive Analysis:

- Use AI to predict and prevent potential security breaches before they occur.

Application:

- Protecting sensitive pharmaceutical research and patient data from cyber threats by proactively identifying and mitigating potential breaches.

Basics of AI: From Data Collection to Results

Step 1: Opportunity Identification
- Define the Task
- Identify Goals
- Understand Requirements

Step 2: Data Collection
- Gather Relevant Data
- Ensure Data Diversity
- Prioritize Quality Sources

Step 3: Data Processing
- Clean the Data
- Organize Information
- Format for Analysis

Step 4: Algorithm Selection
- Choose Appropriate Models
- Consider Task Complexity
- Evaluate Efficiency

Step 5: Model Training
- Feed Data into the Model
- Adjust Parameters
- Optimize Performance

Step 6: Testing and Validation
- Assess Model Accuracy
- Cross-Validate Results
- Ensure Reliability

Step 7: Iteration and Improvement
- Refine Algorithms
- Enhance Data Quality
- Optimize Parameters

Step 8: Deployment
- Integrate into Systems
- Monitor Real-World Performance
- Ensure Scalability

Step 9: Feedback Loop
- Collect User Feedback
- Analyze Performance Data
- Update the Model Accordingly

Step 10: Continuous Learning
- Adapt to New Data
- Evolve with Requirements
- Maintain Relevance
- Evaluation

Artificial Intelligence
DO I NEED IT?

AI

Opportunity Complexity

Data Availability

Scalability

Cost-Benefit Analysis

Expertise

Alternative Solutions

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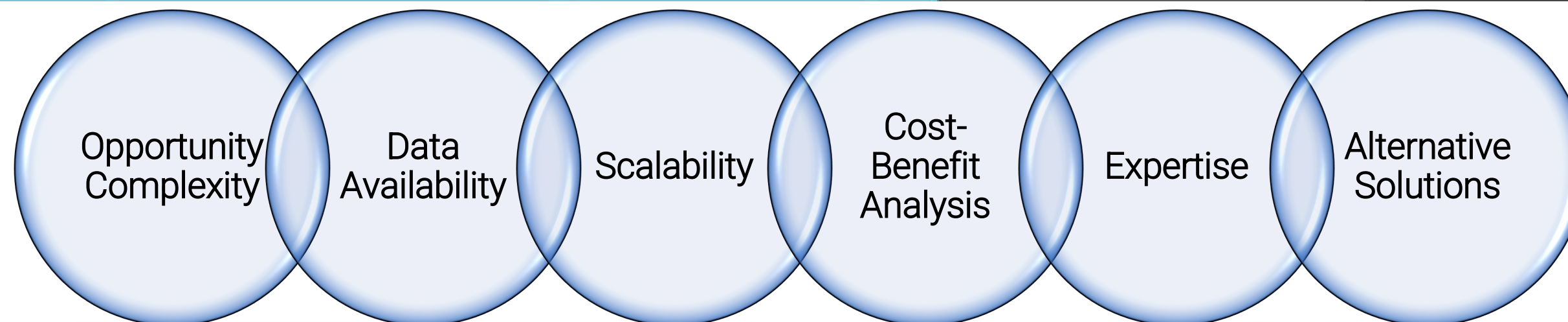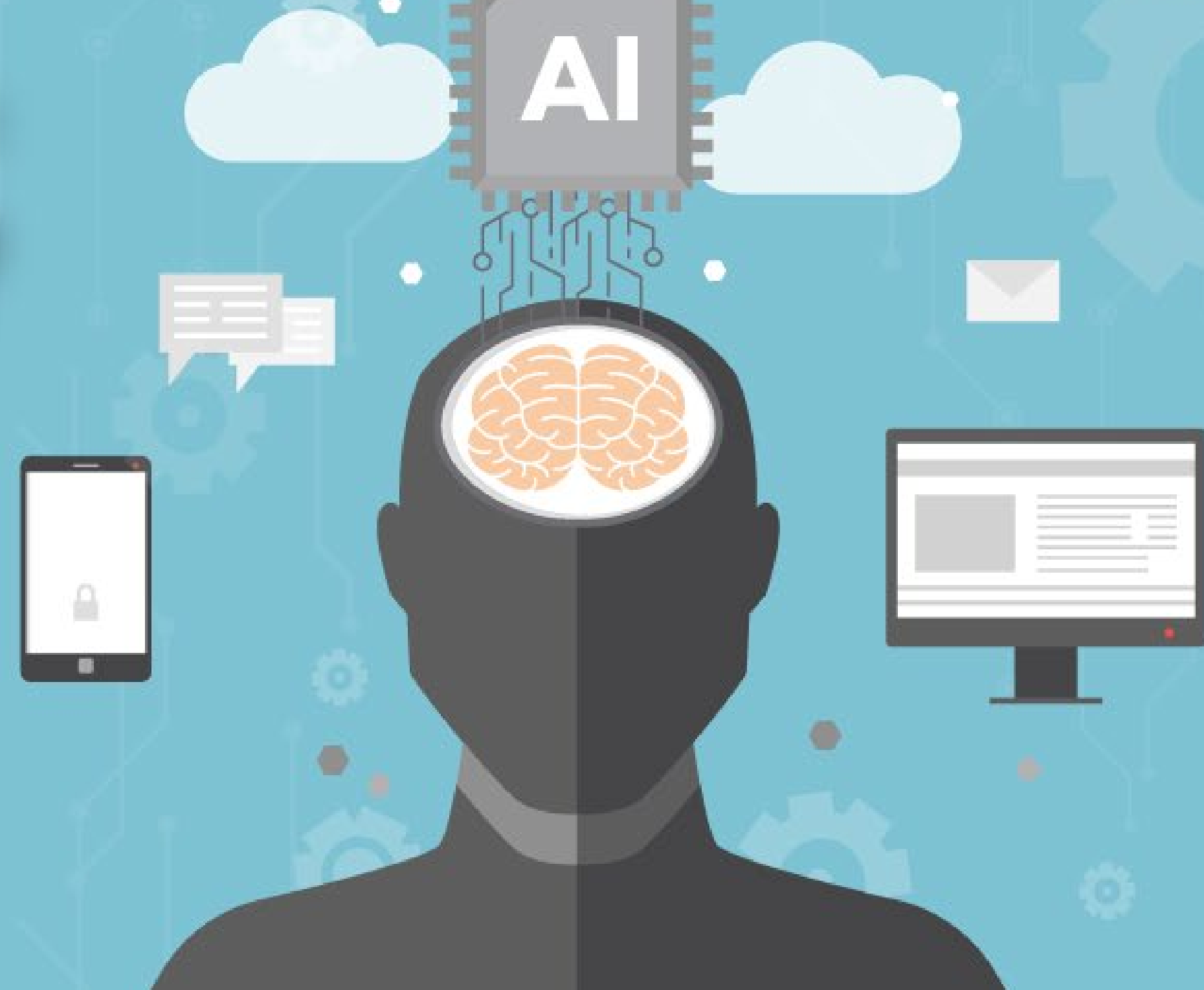
Opportunities Of AI Within Pharma

Manufacturing and Production

- Process Optimization:
  - Automate and streamline workflows to enhance productivity and equipment effectiveness.
- Quality Control:
  - Real-time inspections to detect defects.

Innovation in Manufacturing Processes

- Accelerate Development:
  - Analyze data to optimize manufacturing processes and reduce production times.
- Scheduling:
  - Implement smart scheduling to minimize downtime and improve resource allocation.

Quality and Compliance

- Consistency in Operations:
  - Adjust processes in real time to maintain high-quality standards.
- Regulatory Compliance:
  - Help generate detailed compliance reports for each manufacturing step.

Safety and Maintenance

- Predictive Maintenance:
  - Monitor equipment to anticipate maintenance needs and avoid failures.
- Workplace Safety:
  - Enhance safety through AI monitoring and assistive technologies for handling heavy tasks.

Supply Chain Management:

- Forecasting and Logistics:
  - Predicts demand accurately and optimizes stock levels and logistics, preventing drug shortages.

Document Control

- SOPs, Compliance and Investigations:
  - Manage and update SOPs efficiently using AI to ensure compliance.

Challenges of AI

Data Quality and Integration

- High-Quality Datasets
  - AI needs accurate, complete, and relevant data.
- System Integration
  - Integrating AI with existing IT systems is complex.

Regulatory Compliance

- AI must comply with strict pharmaceutical regulations.
- Regular checks are essential for AI accuracy and safety

Ethical Considerations

- Data Privacy and Fairness
  - Protect patient data and ensure fair AI outcomes.
- Transparency & Accountability
  - Ensure understandable and traceable AI decisions.

Scalability and Interoperability

- As AI applications expand, ensuring that systems can scale efficiently is critical.
- Managing larger datasets or integrating AI across global operations.

Human-AI connection

- Cultural Resistance (AI as a tool, not as a replacement)
- Adaptation and Training
- Trust in AI Decisions
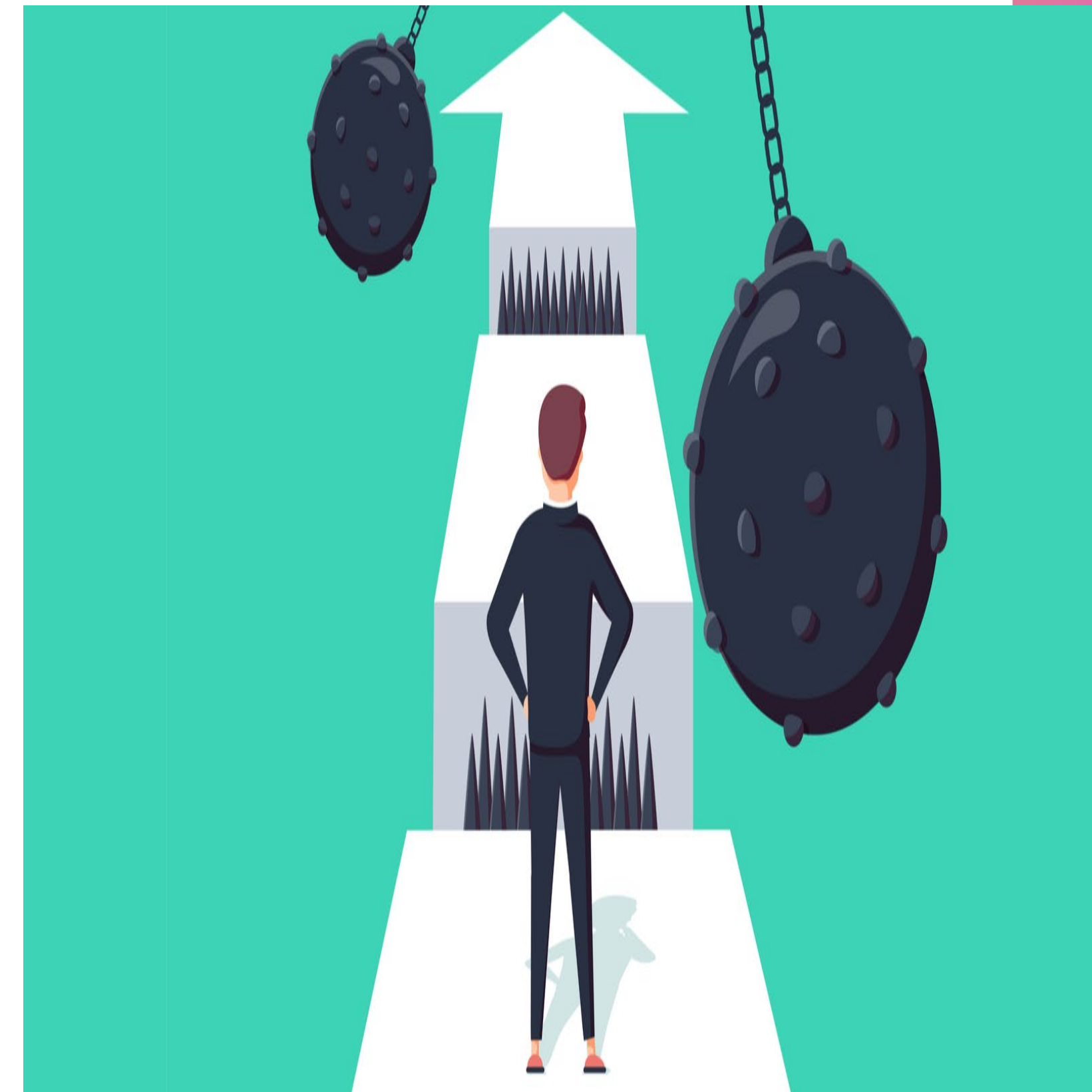
AI Ethics and Potential Implications in Pharma

Ensuring Fairness and Equity

Non-Discrimination: Ensuring AI systems do not discriminate.

Accessibility: Designing AI tools to be accessible to all.

Implications for Workforce

Human Oversight: Maintaining a balance between automation and human involvement.

Training and Education: Continuous training programs for employees.

Data Privacy and Security

Safeguarding Patient Data: Implementing strict data privacy measures.

Cybersecurity Measures: Deploying robust cybersecurity protocols.

Trust and Acceptance

Building Trust: Establishing transparent AI systems.

Engagement with Stakeholders: Involving stakeholders in AI development and deployment.

AI Governance

Internal Governance Programs

- Data Privacy and Security:
  - Protect sensitive information.
- Ethical AI Frameworks:
  - Ensure transparency, fairness, and accountability.
- Accountability and Oversight:
  - Define clear roles and responsibilities.
- Guidelines:
  - Provide responsible AI use guidelines.
- Implementation:
  - Training, continuous monitoring, and regular reporting.
- Multidisciplinary Teams:
  - Combine AI, IT, and operations expertise.
- Algorithm Inaccuracies:
  - Identify biases through rigorous testing.
- Success Thresholds:
  - Establish performance metrics.
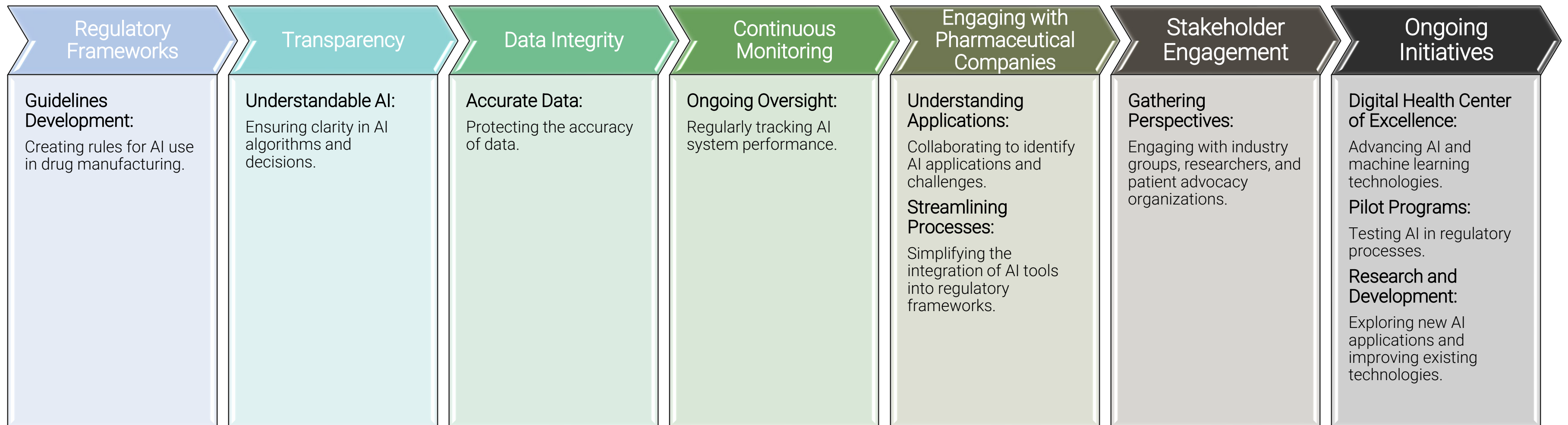
Third-Party Collaboration:

- Unbiased evaluation of AI systems
- Independent Verification like Auditors and Third-Party Experts
  - Conduct independent verification and validation for assurance
- Benchmarking
  - Use industry-standard benchmarks and protocols to test AI systems.

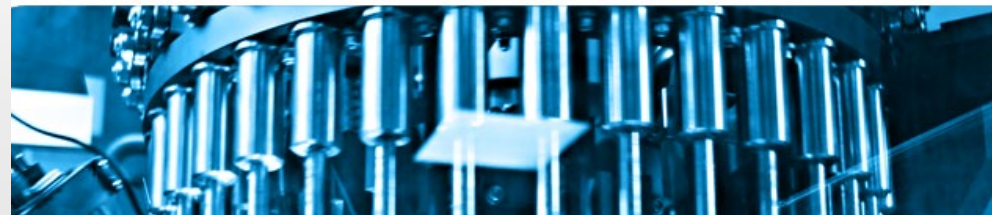proQuality Network
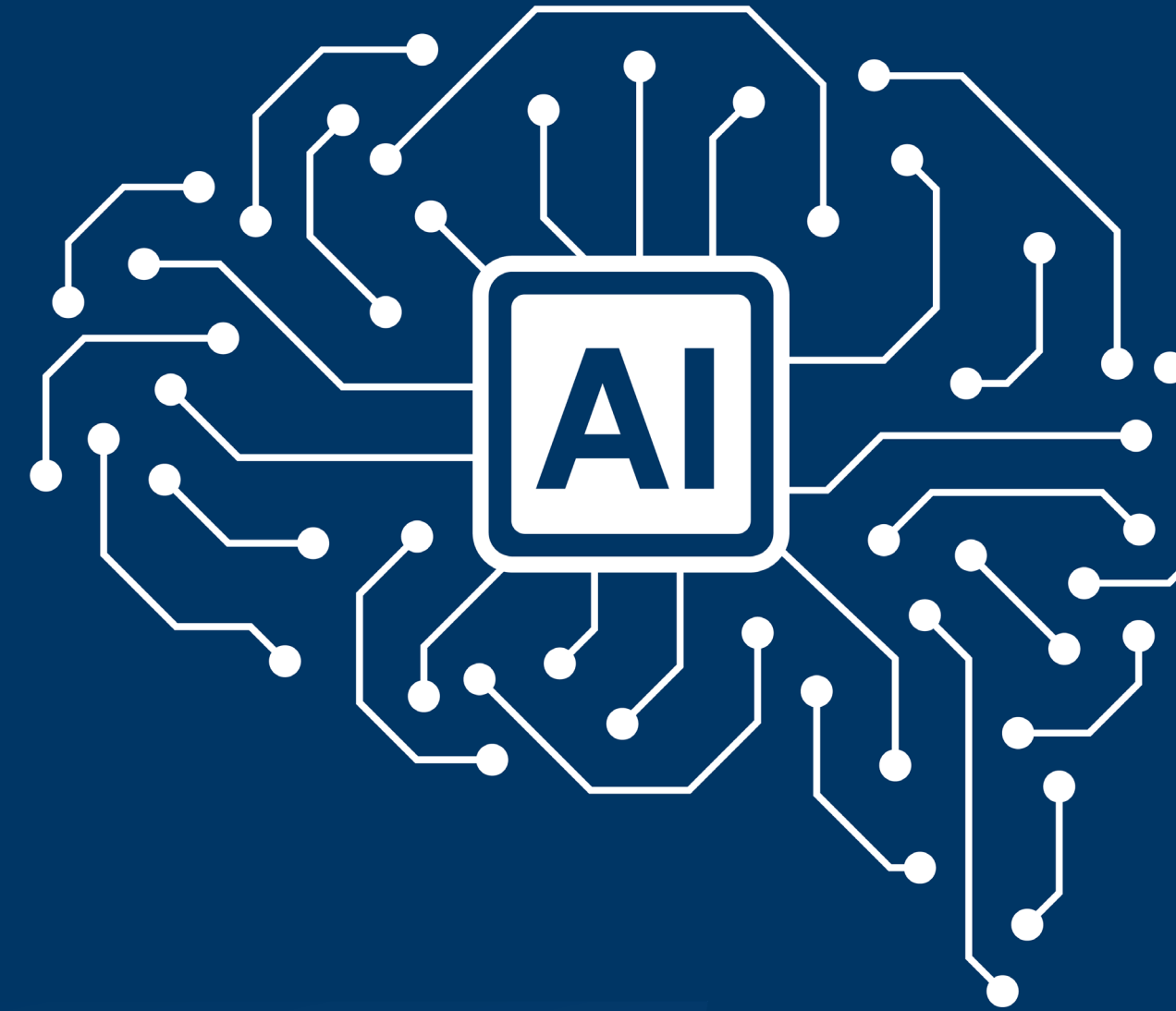
What Does The FDA Say About AI?

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FDA's Role in AI for the Pharmaceutical and Medical Device Industries

Regulatory Frameworks

Guidelines Development:

Creating rules for AI use in drug manufacturing.

Transparency

Understandable AI:

Ensuring clarity in AI algorithms and decisions.

Data Integrity

Accurate Data:

Protecting the accuracy of data.

Continuous Monitoring

Ongoing Oversight:

Regularly tracking AI system performance.

Engaging with Pharmaceutical Companies

Understanding Applications:

Collaborating to identify AI applications and challenges.

Streamlining Processes:

Simplifying the integration of AI tools into regulatory frameworks.

Stakeholder Engagement

Gathering Perspectives:

Engaging with industry groups, researchers, and patient advocacy organizations.

Ongoing Initiatives

Digital Health Center of Excellence:

Advancing AI and machine learning technologies.

Pilot Programs:

Testing AI in regulatory processes.

Research and Development:

Exploring new AI applications and improving existing technologies.

Understanding Artificial Intelligence

Now what?

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Steps for Implementing AI

Develop a Strategic AI Plan:
- Identify key areas where AI can have the most significant impact.
- Set clear objectives and goals for AI implementation.
- Align AI initiatives with overall business strategy.

Invest in Data Infrastructure:
- Ensure high-quality, comprehensive datasets for training AI models.
- Implement robust data management and governance practices.
- Establish a secure and scalable data infrastructure.

Build a Skilled Workforce:
- Offer training and development programs focused on AI technologies.
- Upskill current employees to work effectively with AI systems.
- Collaborate with educational institutions to create relevant curricula.

Foster Collaboration:
- Engage with AI experts, industry partners, and regulatory bodies.
- Participate in industry consortia and research initiatives.

Implement Ethical AI Practices:
- Develop and enforce ethical guidelines for AI use.
- Ensure transparency, fairness, and accountability in AI systems.
- Conduct regular audits to identify and mitigate biases.

Enhance Regulatory Compliance:
- Stay updated with evolving regulations and guidelines.
- Work closely with regulatory authorities to ensure compliance like the FDA.
- Automate documentation and reporting processes.

Monitor and Iterate:
- Continuously monitor AI systems for performance and compliance.
- Collect feedback and make data-driven improvements.
- Stay agile and adapt AI strategies as technologies and regulations evolve.

Promote a Culture of Innovation:
- Encourage experimentation and innovation within the organization.
- Recognize and reward successful AI initiatives.
- Cultivate an environment that embraces change and new technologies.
- Share best practices and collaborate on AI standards.

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Conclusion

AI is here to stay.

AI is a tool that **augments human decision-making and enables risk management** – it does not replace humans.
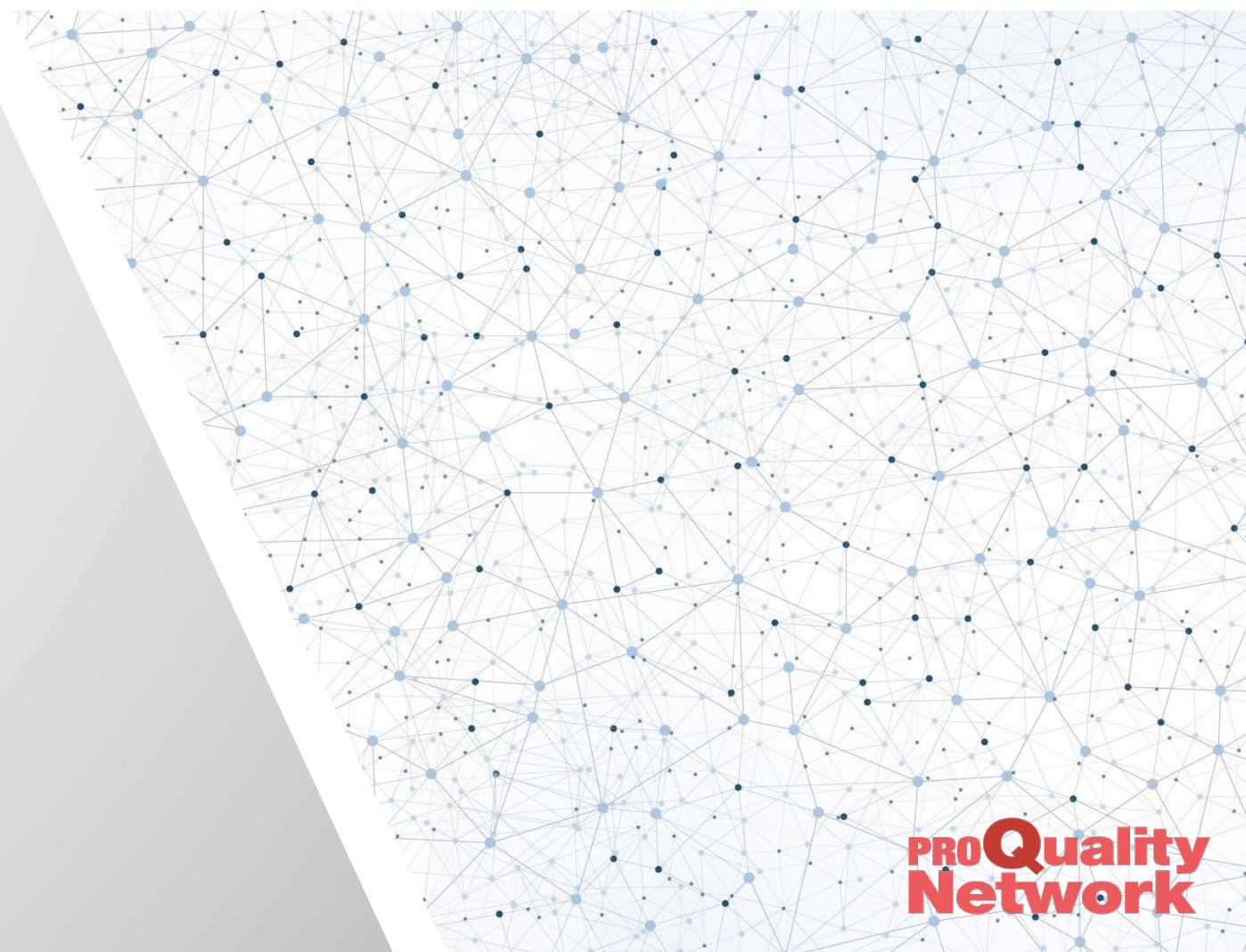
Companies embracing AI systems will have a **competitive advantage**.

AI implementation is not just a technological upgrade but a **strategic necessity**.

We need to embrace the future with AI because the future is now.

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Scan to connect