Artificial Intelligence in Healthcare Services Sector
A Global Regulatory Perspective

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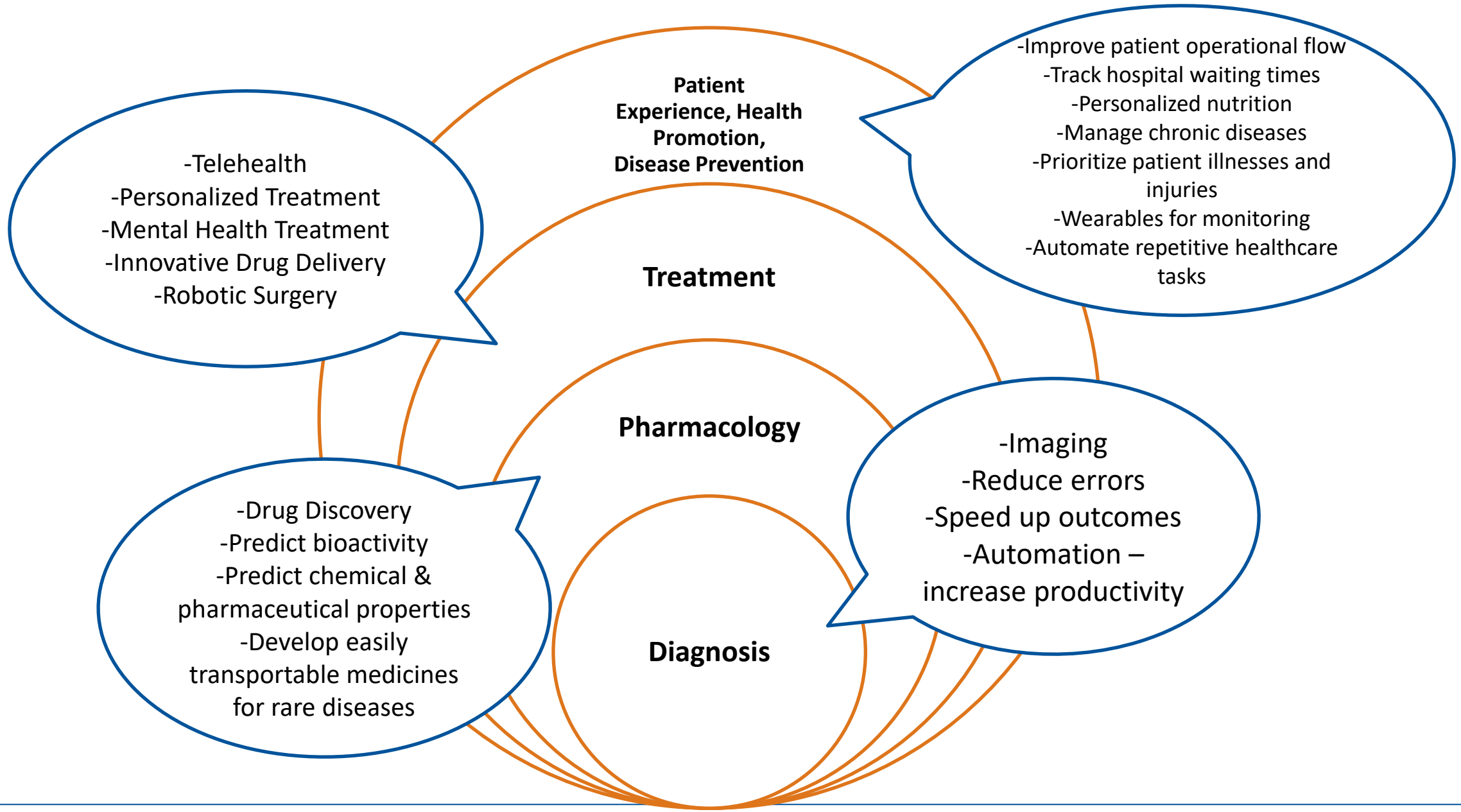
What is Artificial Intelligence (AI)?

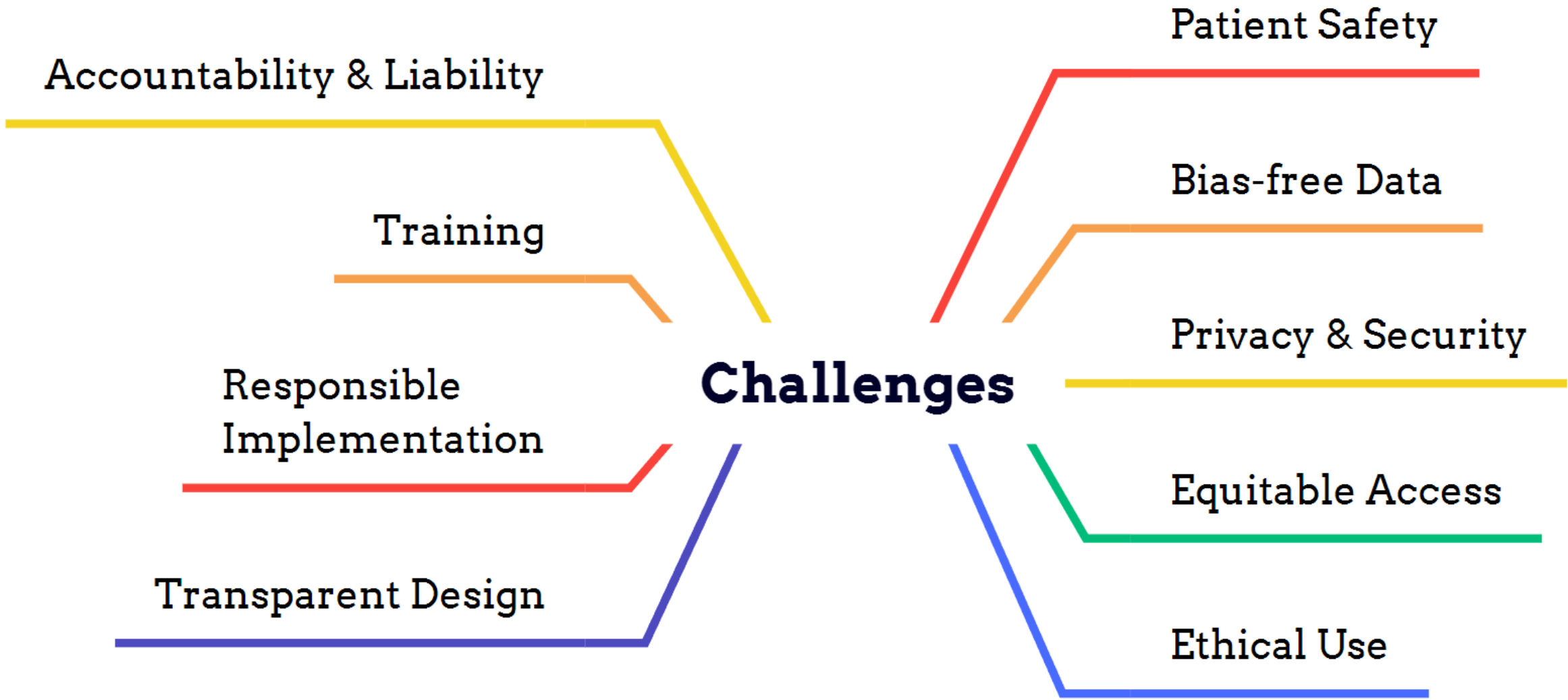
As per the Encyclopedia Brittanica, AI is “the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings” (source: Copeland, B. (2023). *artificial intelligence*. *Encyclopedia Britannica*. https://www.britannica.com/technology/artificial-intelligence)

Broadly, AI can be defined as the capability of a machine to learn from experiences (in the form of inputs by humans) and perform human-like tasks.

Applications of AI in Healthcare



Challenges in Regulating AI



Existing Regulatory Frameworks for AI

- Majority of regulations revolve around the health products angle
  - Applies to Software as Medical Devices (SaMDs)
  - Does not apply to:
    - ➔ Software that provides clinical support or recommendations to healthcare professionals
    - ➔ Software that is intended to help people maintain a health lifestyle
    - ➔ Software used for administrative support
- US FDA, Australia, New Zealand, Singapore, China – use the Total Product Life Cycle approach
- European Commission and Brazil – use a Risk-based approach

Complexity of AI

- Nature and functionality of AI-based medical devices are more complex
  - Algorithms used in AI have capability to
    - ➔ work autonomously
    - ➔learn continuously
    - ➔change their results over time based on new datasets
  - Results from a testing environment may be totally different from actual practice settings

New Terminologies used in the field of AI

Data Exportation

Data Colonization

Explainability

Causability

Methodology

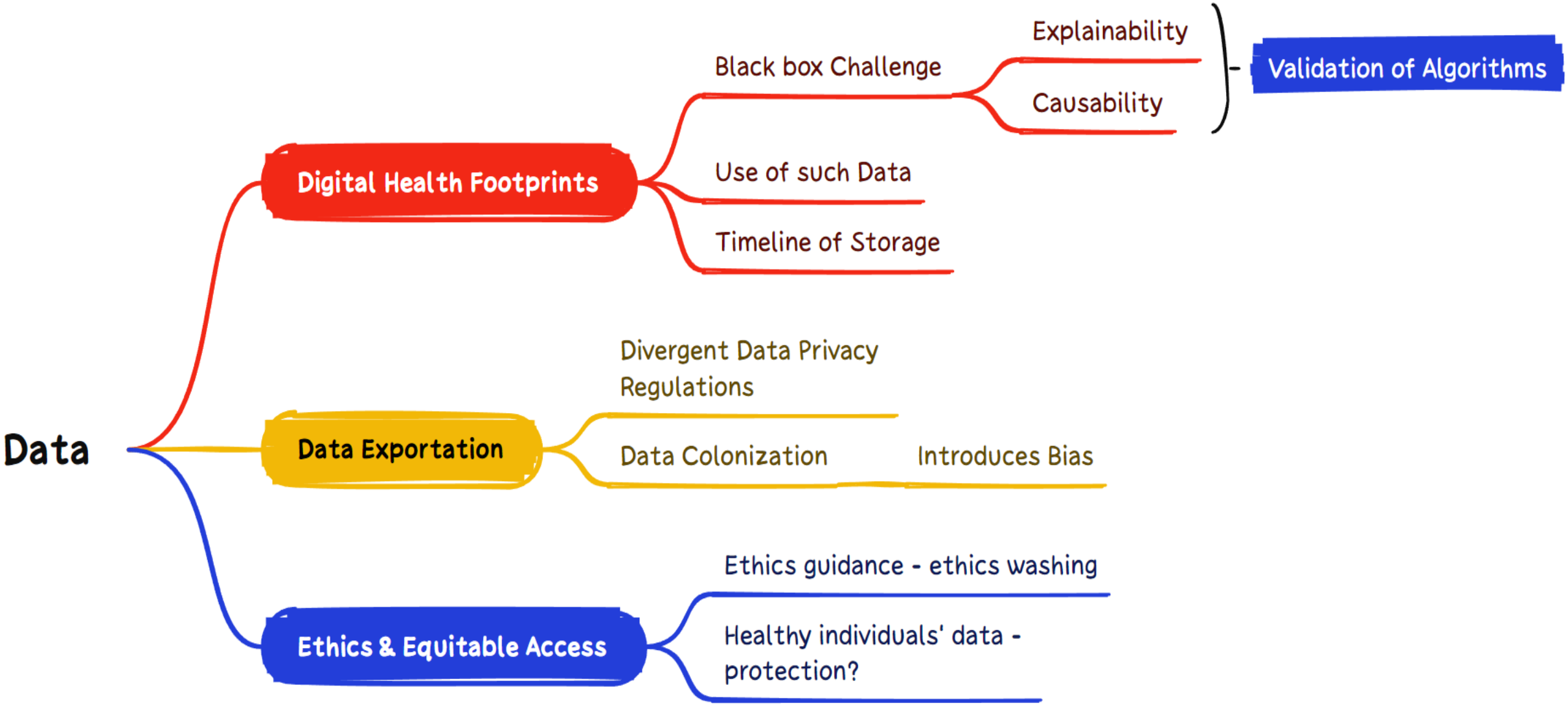
- Aim of the study
  - The aim of this study was to review the literature pertaining to the regulations and regulatory gaps in AI for healthcare services

- Methodology
  - Literature Review to identify the regulatory gaps in AI for healthcare services
  - Challenges used as search strings
  - Journal articles and grey literature over the past 23 years reviewed
  - Regulatory gaps classified under 5 major domains

Domains of Regulatory Gaps

1. Data Quality
2. Validation of Algorithms
3. Data Security and Protection
4. Ethics and Equitable Access
5. Accountability and Liability

Data Security, Protection & Quality



Accountability & Liability

Further complicated when physician and patient are located in different countries that are governed by different sets of regulations!

Legal Liability

- Physician? → Makes a mistake in using the technology after going through training
- Premise? → Decides to use a particular AI technology
- Personified AI Algorithm?
- Developer? → Errors in the algorithm computation

DTC AI healthcare services – additional burden on healthcare systems, social cost implications

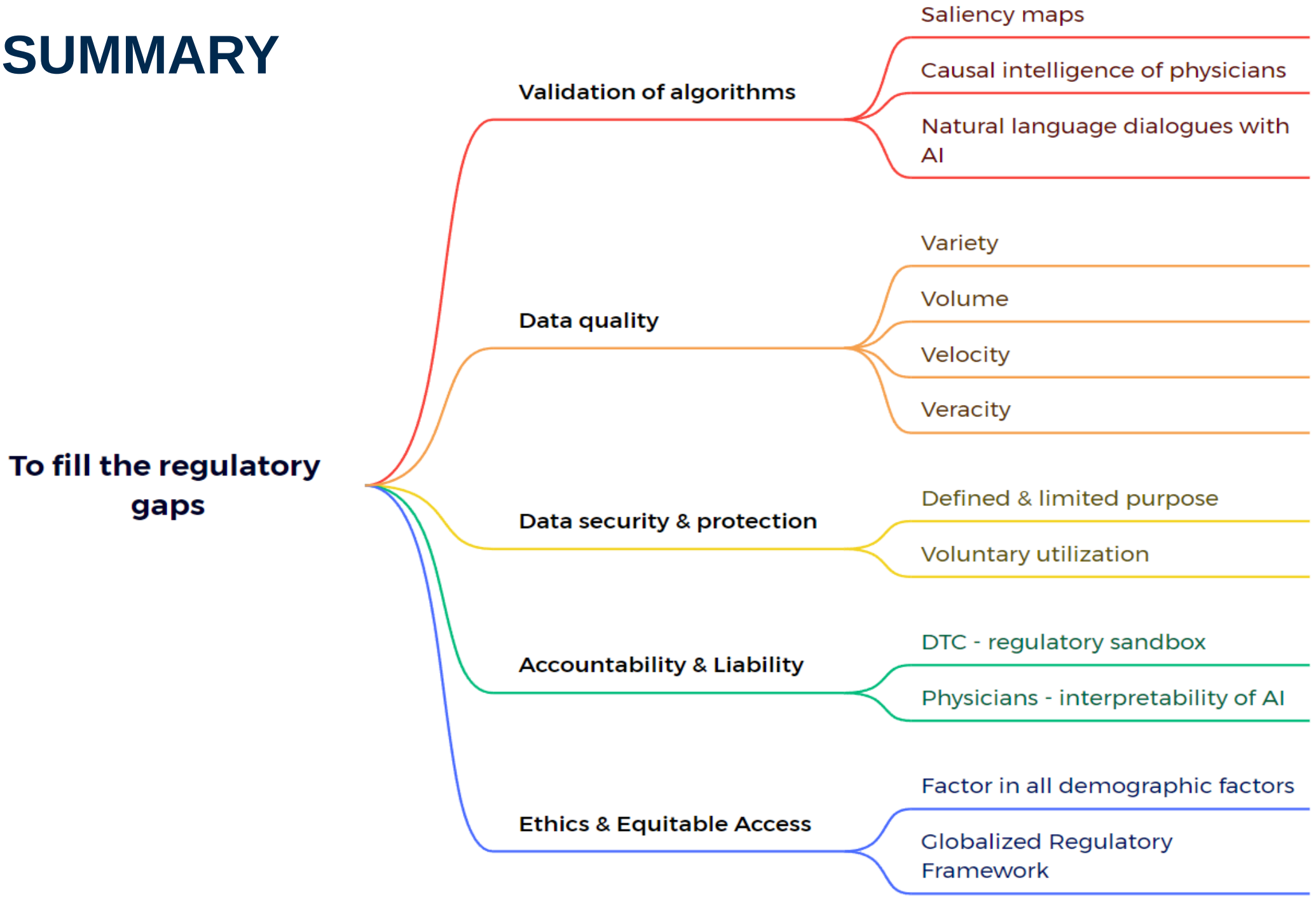
Moving Forward – Regulatory Perspective Suggestions

- FDA's Total Product Life Cycle Approach could be adopted as in Total Service Life Cycle Approach for AI in healthcare services:
  - Specified performance objectives
  - Defined algorithm change protocols
  - Real-world monitoring of performance ensures safety, effectiveness & improvement
  - AI health service remains compliant as long as it continues to improve in the path as predicted by the manufacturer

Moving Forward – Regulatory Perspective Suggestions

- EC's AI Act & Brazilian Legal Framework for AI – Draft AI Law
  - Risk-based approach – healthcare – high-risk AI
    - ➔Require maintenance of a publicly accessible database of completed risk assessments
    - ➔Conduct periodically repeated algorithmic impact assessment
    - ➔Providers are strictly liable for any damages caused by the AI system

SUMMARY


To fill the regulatory gaps
Validation of algorithms
Saliency maps
Causal intelligence of physicians
Natural language dialogues with AI
Data quality
Variety
Volume
Velocity
Veracity
Data security & protection
Defined & limited purpose
Voluntary utilization
Accountability & Liability
DTC - regulatory sandbox
Physicians - interpretability of AI
Ethics & Equitable Access
Factor in all demographic factors
Globalized Regulatory Framework

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Thank You