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Source:	WHO
Title:	Att.3 – Presentation - Overview of the Regulatory Considerations on AI4H
Purpose:	Discussion

Contact:	Shada Alsalamah	E-mail: alsalamahs@who.int

Abstract:	This PPT contains a presentation from the workshop on AI for health on “Regulatory Concepts”.

World Health Organization

Regulatory Concepts on AI for Health

Shada AlSalamah, PhD

FG- AI4H - Meeting P - Helsinki

20/09/2022

AI for Health
An ITU Focus Group
In collaboration with WHO

WG-RC DEL 02- Purpose & Scope

- A general high-level overview of non-inclusive key regulatory considerations for the use of AI in health.
- A resource that can be considered by regulators, developers, and other stakeholders.
- Not intended to be a guidance, regulation, or policy.
- Dialogue between developers and regulators to establish a common understanding around the use of the AI solutions in health

Topic Areas for Regulatory Considerations*

1. Documentation and Transparency
2. Risk Management & AI Systems Development Lifecycle Approaches
3. Analytical and Clinical Validation
4. Data Quality
5. Engagement and Collaboration
6. Privacy and Data Protection

* These topic areas are not fully inclusive

1/6 Documentation and Transparency

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- Essential for AI solutions and systems that may be subject to regulatory review.
- **Regulators**
  - Trace back the development process & have evidence and trusted documentation of essential steps and decision points.
- **Systems**
  - Protect against data manipulation & malicious attacks
  - Track and record access and changes applied as appropriate.

1/6 Documentation and Transparency

- Supports and informs regulatory decision making
- Helps identify and guard against bias.
- Creates an opportunity to show the strength of a science-based development.
- Helps establish a shared understanding among all stakeholders.
- Supports confidence and trust in the AI solution and development process.

1/6 Recommendations for Documentation and Transparency

- Consider pre-specifying and **documenting the intended purpose and development process,** such as the selection and use of datasets, reference standards, parameters, metrics, deviations from original plans, and updates, during the phases of development should be considered in a manner that allows for the tracing of the development steps as appropriate.
- Consider a **risk-based approach for the level of documentation** and record keeping utilized for the development and validation of AI systems.

2/6 Risk Management & AI System Development Lifecycle Approaches

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- Aims to present a holistic risk-based approach for the AI system throughout its lifecycle pre- and post-marketing.
- **Covering three areas**
    1. AI system development and deployment process
    2. AI system development lifecycle
    3. Holistic risk management

2/6 Recommendations for Risk Management & AI System Development Lifecycle Approaches

- Consider a **total product lifecycle approach** throughout all phases in the life of a medical device and the key broad management categories: pre-market development management, post-market management, and change management.
- Consider a **risk management approach** that addresses risks associated with AI systems, such as cybersecurity threats and vulnerabilities, underfitting, and algorithmic bias, etc.

3/6 Analytical and Clinical Validation

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1. Intended Use
2. Clinical Validation
3. Analytical Validation
4. Cost effectiveness
5. Post market safety monitoring
6. Low and middle income countries

3/6 Recommendations for Analytical and Clinical Validation

- Consider providing **transparent documentation of the intended use of the AI system**.

  Details of the training dataset composition underpinning an AI system, including size, setting and population, input and output data and demographic composition should be transparently documented and provided to users.

- Consider **demonstrating performance beyond the training data** through external, analytical validation in an independent dataset. This dataset should be representative of the population and setting in which the AI system is intended to be deployed, and transparent documentation of the external dataset and performance metrics should be provided.

3/6 Recommendations for Analytical and Clinical Validation

- Consider a graded set of requirements for clinical validation based on risk. Randomized clinical trials are the gold standard for evaluation of comparative clinical performance and could be appropriate for the highest risk tools or where the highest standard of evidence is required. In other situations, consider prospective validation in a real-world deployment and implementation trial which includes a relevant comparator using accepted relevant groups.

- Consider a period of more intense post-deployment monitoring for adverse events.

4/6 Data Quality

4/6 Considerations for Data Quality

Key Data Challenges

1. Data set management
2. Data inconsistency
3. Data set selection and curation
4. Data usability
5. Data integrity & data labelling
6. Model training
7. Documentation and transparency
8. Human factors

4/6 Considerations for Data Quality

Data Quality Check Principles

4/6 Considerations for Data Quality

Data Quality Considerations

- Data set
- Data infrastructure
- AI/ML model
- Governance management

Category	Data quality consideration item
Dataset	Splitting
	Selection volume and size
	Selection bias
	Individual variables definitions in each dataset
	Raw data vs “cleaned” data
	Data wrangling and cleansing
	Parameters and hyperparameters
	Usability
	Characterization
	Labelling
	Dependencies
	Augmentation
	Manipulation
	Streaming
	Interfaces
	Integrity
	Unique requirements
	Data source
Data Infrastructure	Storage size
	Storage format
	Transformation medium
AI/ ML Model	Data Training
	Tuning Data
	Verification set
	Validation set
	Testing
	Development set
	Static AI vs dynamic AI
	Open AI vs closed AI
Governance Management	Liability
	Data access
	Risk Management
	Data Protection
	Privacy
	Adoption education for clinical practice
	Good practices
	Standards (of care, governance, interoperability, etc.)
	Scope of practice and AI model use
	Technical checklist
	Documentation
	Transparency

4/6 Recommendations for Data Quality

- Consider whether **available data is of sufficient quality to support the development** of the AI system that can achieve the intended goal.
- Consider deploying **rigorous pre-release trials for AI systems** to ensure that they will not amplify any of the issues discussed in Section 4, such as biases and errors.
- Consider **careful design or prompt troubleshooting** to help identify data quality issues early on, which could potentially prevent or ameliorate possible resulting harm.
- Consider **mitigating data quality issues** that arise in healthcare data and the associated risks.
- Consider **working with other stakeholders to create data ecosystems** that can facilitate the sharing of good-quality data sources.

5/6 Engagement and Collaboration

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How does this impact clinical outcomes? Two case studies review findings:

- Clinicians have had direct engagement with regulators for device classifications associated with each trial
- Rapid responses and very informative and helpful engagement from regulatory team has resulted in efficient turnaround times for trial initiation

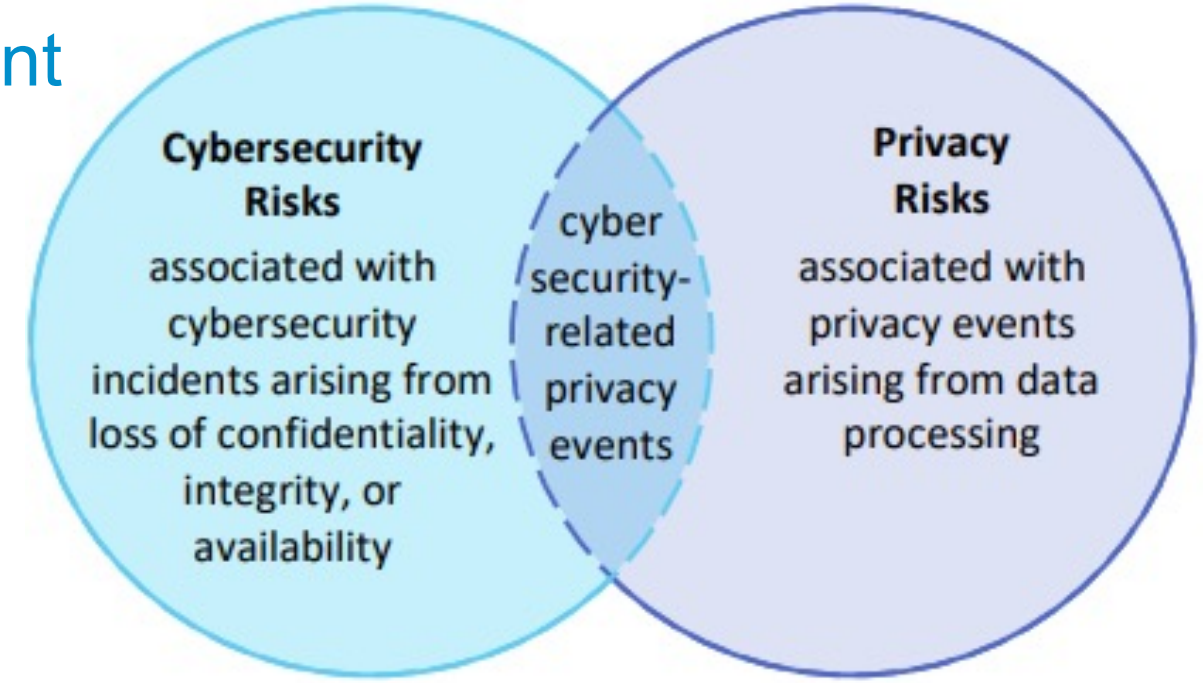
5/6 Recommendation for Collaboration and Engagement

- Consider the **development of accessible and informative platforms** that facilitate engagement and collaboration, where applicable and appropriate, among key stakeholders of the AI innovation and deployment roadmap.
- Consider **streamlining the oversight process for AI regulation** through engagement and collaboration to potentially accelerate practice-changing advances in AI to the user community.

6/6 Privacy and Data Protection

6/6 Privacy and Data Protection

- How can we nurture development of strategies in resource-limited settings?
- **Key Consideration areas**
  - *Quality Continuum*
  - *Risk Assessment*
  - *Annotated Notes and Audit Trial*
  - *Cybersecurity*



NIST Privacy Framework – Cybersecurity and Privacy Risk Relationship

6/6 Privacy and Data Protection

- **Health sources for AI solutions** (*What needs to be protected?*)
- **Regulatory landscape** (*How it should be protected?*)
  - Developers and their companies should
    1. Gain an understanding of applicable data protection regulations and information privacy laws
    2. Consider the different jurisdictions' regulations and laws
    3. Stay current on new laws and requirements

6/6 Recommendations for Privacy and Data Protection

- Consider **privacy and data protection** during the design and deployment of AI systems.
- Consider gaining a **good understanding of applicable data protection regulations** and privacy laws early in the development process.
- Consider a **compliance program** that addresses risks and develop privacy and cybersecurity practices and priorities that take into account potential harm, as well as the enforcement environment.

Final Steps Towards Publication

Final Steps Towards Publication

Targeted Month	Planned Milestones/ Deliverables
September	• *Present at Meeting P* • *Send it to FG management for clearance* • *Publication layout*
October	• *Submit DEL02 draft to WHO editors with final recommendations*

World Health Organization

We must ensure that the Digital Health transformation is safe, sustainable and leaves no one behind.

Alsalamahs@WHO.int

Anup, visually impaired pupil listening at Resource centre for children with visual impairments, Jharkhand, India. WHO/NOOR/Arko Datto