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Source:	WHO	
Title:	Att.5 - Presentation - Regulatory Concepts on AI for Health	
Contact:	Shada Alsalamah Sameer Pujari	E-mail: alsalamahs@who.int E-mail: pujaris@who.int
Abstract:	This PPT contains a presentation on Regulatory Concepts on AI for Health given during the workshop 21 March 2023.	

World Health Organization

Workshop - Regulatory Concepts on AI for Health

FG-AI4H
Boston, MA, USA
Meeting R - 22/03/2023

AI for Health
An ITU Focus Group
In collaboration with WHO

ITU

Workshop Agenda

Shada Alsalamah

Workshop Agenda

13:45-15:00	Session IV - 75 mins	Regulatory Concepts on AI for Health Workshop
13:45-13:50	**Sameer Pujari** (WHO, DHI)	*Context Setting*
13:50-14:05	**Shada Alsalamah** (WHO, DHI)	*Overview of Regulatory Concepts on AI for Health*
14:05-14:35	Moderator: **Sameer Pujari** (WHO, DHI) Panellists: **Marcelo D'Agostino** *(PAHO)* **David Vidal** *(Mayo Clinic)- Virtual* **Shubs Upadhyay** **Andreas Reis** *(WHO)- Virtual* **Bastiaan Quest** *(ITU)* **Junaid Nabi** *(Harvard University) - Virtual*	*Moderated Panel Discussion*
14:35-14:50	**Sameer Pujari** *(WHO, DHI)*	*Q&A*
14:50-15:00	**Shada Alsalamah** *(WHO, DHI)*	*Summary & Next Steps*

Context Setting

Sameer Pujari

Overview of Regulatory Concepts on AI for Health

Shada Alsalamah

The Impactful Engagement Gap

- Although regulators are keen on ensuring that AI solutions are **safe** and **effective** for intended use, and **accessible,** technology is faster than the law.
- There is a need for establishing **a common understanding** and an **engagement** that has impactful outcomes
- A **resource** that can be considered by regulators, developers, and other stakeholders for a general high-level overview of non-inclusive key regulatory concepts for the use of AI in health.

Topic Areas for Regulatory Concepts*

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 Recommendations

- Consider pre-specifying and **documenting the intended purpose and development process,** such as the selection and use of datasets, deviations from original plans, and updates during the phases of development 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 Recommendations

- 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 Recommendations

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

3/6 Analytical and Clinical Validation Recommendations

- 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.

- Consider a **graded set of requirements for clinical validation based on risk**.

4/6 Data Quality Recommendation

- 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 identified issues, such as biases and errors.

4/6 Data Quality Recommendation

- 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.
- Consider **careful design or prompt troubleshooting** to help **identify data quality issues early on**, which could potentially prevent or ameliorate possible resulting harm.

5/6 Collaboration and Engagement Recommendations

- 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 Recommendations

- 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.

Moderated Panel Discussion

Sameer Pujari

Panel Discussion

Panellists

Marcelo D'Agostino
PAHO

David Vidal
Mayo Clinic- Virtual

Shubs Upadhyay
Ada Health

Andreas Reis
WHO - Virtual

Bastiaan Quest
ITU

Junaid Nabi
Harvard University- Virtual

Q&A

Sameer Pujari

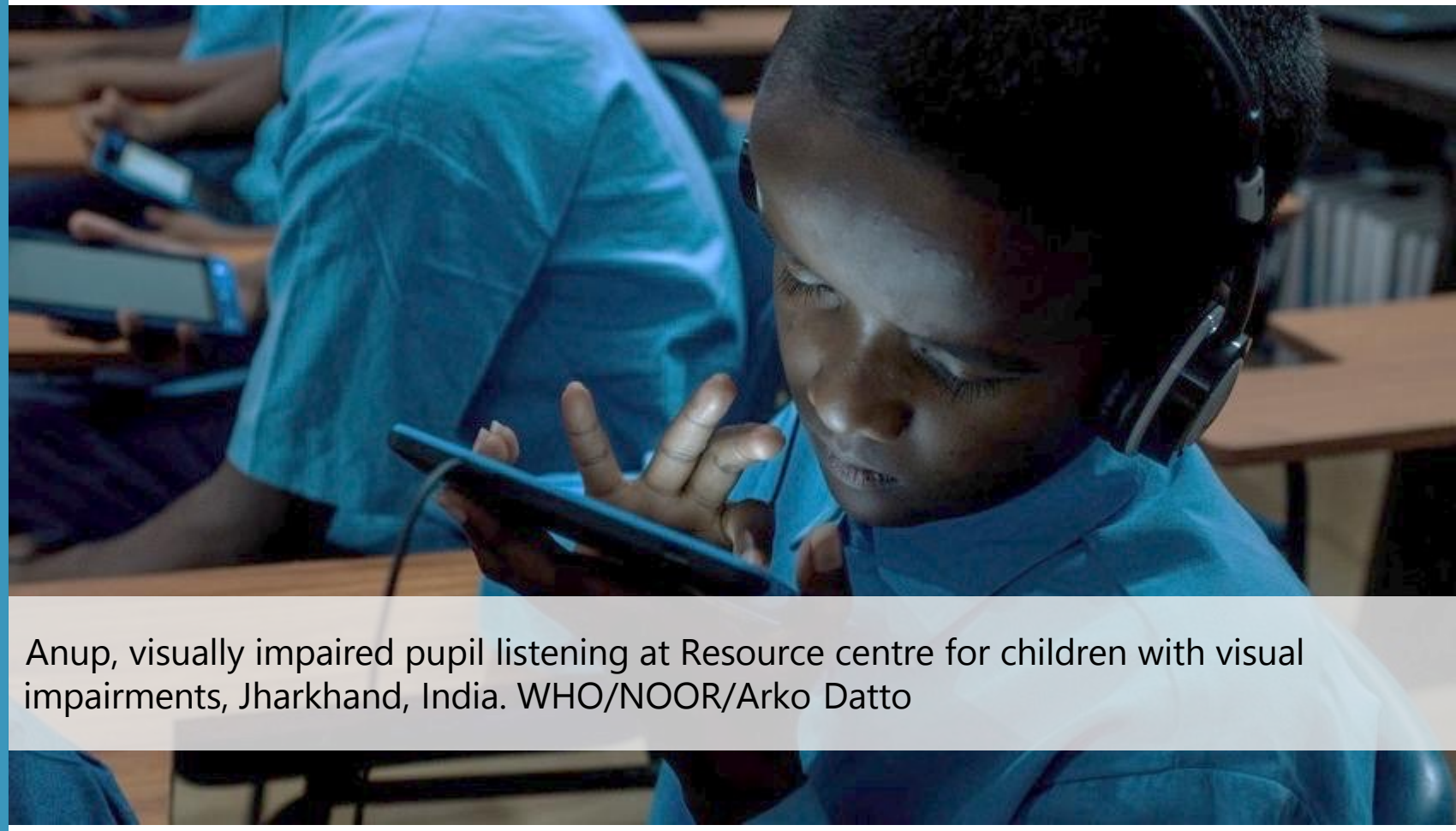
Summary & Next Steps

Shada Alsalamah

World Health Organization

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

{Pujaris, alsalamahs}@WHO.int



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