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HEALTHCARE IT & RADIATION THERAPY  
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**IMDRF** International Medical  
Device Regulators Forum

# IMDRF /DITTA joint workshop

Artificial Intelligence in Healthcare  
*Opportunities and Challenges*

*Monday 16 Sept. 2019, Yekaterinburg*

## How Industry can cope with challenges ?

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# TYPES OF AI IMPLEMENTATION

- **“locked” algorithm:**

SW that has been trained before placing on the market

- **“adaptive” algorithm:**

SW that is continuously adapting and optimizing device performance after placing on the market





# DATA REQUIREMENTS

## Volume/Quantity

Essential, but not sufficient

- Greater volume increases performance
- However, volume must be "balanced", meaning equal positives & negatives
- Better annotation approaches can increase AI performance with volume staying constant (See "Veracity")

| Method | Training Data | Test Accuracy | Test AUC    |
|--------|---------------|---------------|-------------|
| 1      | 286+, 286-    | 0.725         | 0.803       |
| 2      | 600+, 9000-   | 0.755         | 0.844       |
| 3      | 750+, 750-    | 0.785         | 0.879       |
| 4      | 1283+, 1283 - | 0.863         | <b>0.92</b> |

## Variety

Prevents biased & brittle AI

- AI models only work on the type of population they were originally trained on
- If only one data source is used... the result is "brittle", meaning it will perform well at location A where it was trained, but poorly at B
- Lack of diversity will introduce bias



Global Examples



Darker Contrast



Hand in FoV



Poor Positioning

## Veracity

**Clinical relevance ... & top performance**

- Prevents "garbage in, garbage out"
- Essentially, even a high volume of data from all over the world will fall short if the appropriate "ground truth" isn't added
- Can allow for higher performance, with less data fed into the AI model

|                     | Method                    | Time to Annotate | Test Acc     | Test AUC     |
|---------------------|---------------------------|------------------|--------------|--------------|
| Weak<br>↓<br>Strong | Image Level Label         | Fast             | 0.808        | 0.924        |
|                     | Pixel Level ROIs          | Slow             | 0.890        | 0.968        |
|                     | Image Level Label + Pixel | Slowest          | <b>0.929</b> | <b>0.981</b> |

CLASSIFICATION



CAT

DETECTION



CAT

SEGMENTATION



CAT, DOG, DUCK



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# ACCESS TO DATA

- Access to data should be publicly available
- Access to data should be offered at no-cost or if not possible, at a minimum reasonable cost
- Data should be made available in a non-discriminatory way, with market players having equal opportunities to access data





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# REGULATORY MATTERS

- « Locked algorithm »:
  - Only a specific case of Software As a Medical Device (SaMD)
  - Performances and safety characteristics are validated and frozen before placing on the market
  - Classification model of Medical Device Regulations applies
  - SaMD: Quality System, Essential Principles, Risk categorization and Clinical Evaluation apply
  - Standardisation work ongoing (eg. Good Machine Learning Practices)





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# REGULATORY MATTERS

- « Adaptive algorithm »: **differs from other SaMD**
  - Changes in performances and safety characteristics during use
  - How to determine and manage change ? Significant/non-significant change ?
  - How would change to AI system affect regulatory obligations: labelling, registration, ..
  - Requires practical guidance for manufacturers under EU Medical Devices regulatory framework:
    - Application of MDR General Safety and Performance Requirements
    - Conducting clinical evaluation and clinical investigations
    - Change control
  - FDA proposed a regulatory framework for modifications to AI/ML software:
    - Types of SW modifications
    - Total product lifecycle regulatory approach





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# LEGAL MATTERS

- Liability: Decision support vs Autonomous systems
  - Liability shared between manufacturer and medical professional
  - Various scenarios
- Data Protection and Privacy Laws: GDPR
  - Design constraints in terms of data access, transparency, interoperability
- Intellectual Property
  - Manufacturer owns IP on AI systems but not on data used to train the system
  - IP sharing to be addressed in advance by manufacturer in relation with clinical advisers







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# ETHICAL

- AI4People: multi-stakeholder forum
- Ethical Framework builds upon 5 main principles:
  - Beneficence (“do good”)
  - Non-maleficence (“do no harm”)
  - Autonomy (“preserve human agency”)
  - Justice (“be fair”)
  - Explicability (“operate transparently”)

-  Be designed for the benefit, safety and privacy of the patient
-  Be a trusted steward of the data and insights
-  Be transparent and deliver robust and reproducible results
-  Guard against creating or reinforcing bias



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# ETHICAL

- EU Ethics guidelines for trustworthy AI  
AI systems should meet 7 key requirements:
  1. Human agency and oversight
  2. Technical robustness and safety
  3. Privacy and data governance
  4. Transparency
  5. Diversity, non-discrimination and fairness
  6. Societal and environmental well-being
  7. Accountability





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Thank you!  
Спасибо!

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