DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

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

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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")

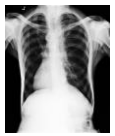
Method	Training Data	Test Accuracy	Test AUC
1	286+, 286-	0.725	0.803
2	600+, 9000-	0.755	0.844
3	750+, 750-	0.785	0.879
4	1283+, 1283 -	0.863	**0.92**

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

Weak ↓ Strong

Method	Time to Annotate	Test Acc	Test AUC
Image Level Label	Fast	0.808	0.924
Pixel Level ROIs	Slow	0.890	0.968
Image Level Label + Pixel	Slowest	**0.929**	**0.981**

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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”)

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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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